

5.1.2 Detailed report of the Capacity enhancement programs and other skill development schemes



Mahatma Gandhi Mission's  
**MEDICAL COLLEGE**  
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 DEPARTMENT OF BIOCHEMISTRY

**Name of the Event: -Soft skills Development**

Event Date:	4/9/23, 5/9/23
Venue:	Lecture Hall 6, 5th Floor
Organized by:	Foundation Course Committee, BIOCHEMISTRY Dept
Objectives:	To teach the students the values of : 1. Time management 2. Stress management 3. Leadership skills
Number of Participants:	Total number of students:183 Total number of Faculty members: 02
Event Summary:	The above-mentioned objectives were achieved successfully.
Feedback :	Taken at the end



Lecture: Stress Management



Lecture: Leadership Skills

Signature of event coordinator (NSS unit coordinator/Student council coordinator etc)

Signature of Criterion V Coordinator/Incharge of the Institute

Signature of Institute's IQAC Coordinator

Signature of Head of Institute

**Co-ordinator  
 IQAC**  
**MGM Medical College & Hospital**  
**Kamothe, Navi Mumbai - 410 209.**

**Dean**  
**MGM Medical College & Hospital**  
**Kamothe, Navi Mumbai-410209**

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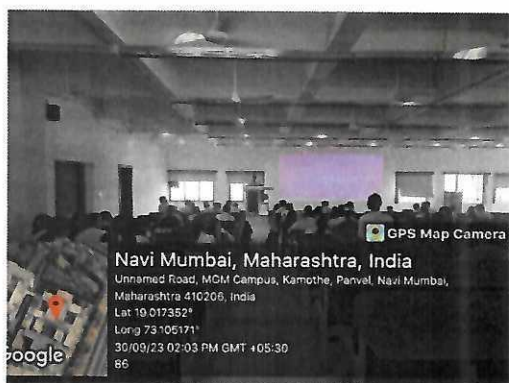
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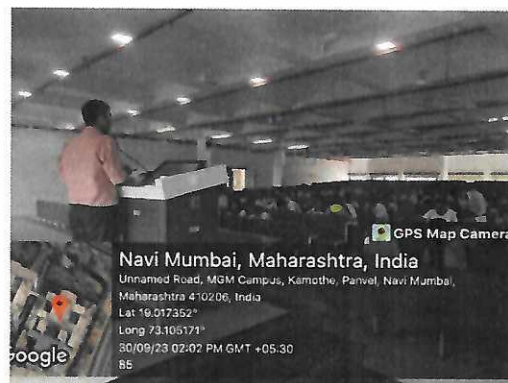
**DEPARTMENT OF BIOCHEMISTRY**

**Name of the Event: - Language and communication skill development**


Event Date:	05/09/23, 30/09/23, 28/10/23, 16/12/23, 23/12/23
Venue:	Lecture hall 5, 5 <sup>th</sup> floor
Organized by:	Foundation Course Committee, BIOCHEMISTRY Dept
Objectives:	<ol style="list-style-type: none"> <li>1.To enable the Ist MBBS students so as to communicate with patients in local language.</li> <li>2.To enable the students to understand the symptomatology of local patients.</li> <li>3.To enable the hostelite students to acquire healthy communication.</li> <li>4. To enable effective communication with peers</li> </ol>
Number of Participants:	Total number of students: 184 Total number of Faculty members:01
Event Summary:	<p>200 students were divided into 2 groups i.e. group which knows local language &amp; the one which doesn't know.</p> <p>Orientation to the terminologies for various symptomatology in the local language, pronunciation, literal meaning &amp; sentence framing in local language was taught.</p> <p>Role play in local language was performed by the learning group.</p> <p>Learning was assessed by viva-voce by translating the English terminology into local language terminology</p>
Feedback (if applicable):	Taken at the end





Lecture: Communication skills



Language session

  
Signature of event coordinator (NSS unit coordinator/Student council coordinator etc)

  
Signature of Criterion V Coordinator/Incharge of the Institute

  
Signature of Institute's IQAC Coordinator

  
Signature of Dean of Institute  
**Dean**  
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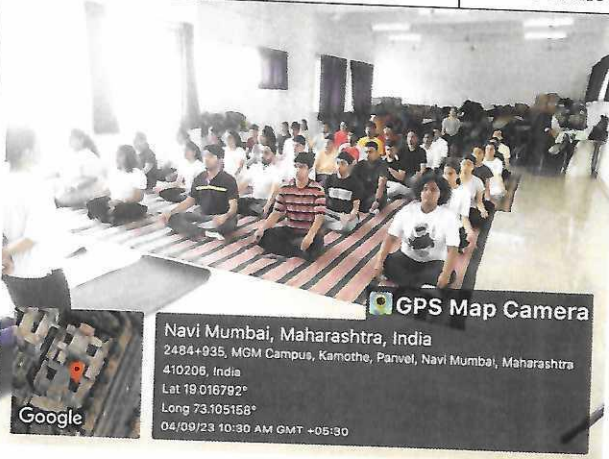
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**Name of the Event – Yoga and Wellness**

<b>Event Date:</b>	02/09/23, 04/09/23, 05/09/23, 06/09/23, 07/09/23
<b>Venue:</b>	MGM Auditorium, 3 <sup>rd</sup> Floor
<b>Organized by:</b>	Foundation Course Committee, BIOCHEMISTRY Dept
<b>Objectives:</b>	Yoga in medical curriculum shall help in <ul style="list-style-type: none"> <li>To improve attention, memory, learning efficacy</li> <li>To deal with depression &amp; anxiety amongst the students.</li> <li>To improve the mental &amp; physical health of the students</li> </ul>
<b>Number of Participants:</b>	Total number of students:143 200 students were divided into 5small groups (A-E) Total number of Faculty members:4
<b>Event Summary:</b>	Yoga + SAHAJ yoga classes were conducted successfully as a part of Foundation course to achieve the above objectives.
<b>Feedback (if applicable):</b>	It was done as reflection writing in the foundation course logbook



Yoga Session



Session on Sahaj Yoga

Signature of event coordinator (NSS unit coordinator/Student council coordinator etc)

Signature of Criterion V Coordinator/Incharge of the Institute

Signature of Institute's IQAC Coordinator

Signature of Head of Institute

**Co-ordinator**  
**IQAC**

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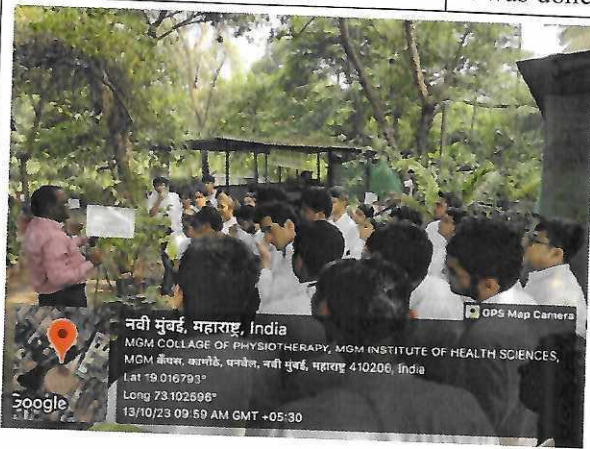


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**Name of the Event – Human Value Development**

Event Date:	04/09/23, 05/09/23, 09/09/23, 13/10/23
Venue:	Lecture hall 6, 5 <sup>th</sup> floor
Organized by:	Foundation Course Committee, BIOCHEMISTRY Dept
Objectives:	<ul style="list-style-type: none"> <li>To help students focus on the basics of Universal Precautions, Primary healthcare systems, National Health Policies, Environmental Consciousness (Visit to Herbal Garden) and disability and rehabilitation systems</li> <li>To build and nurture inter personal relationship and how to cope with peer pressure and study dynamics</li> <li>To help students understand the effects of Health hazards in the society and the role of nutrition</li> <li>To help students realize the health issues faced by medical students and how to prevent it</li> </ul>
Number of Participants:	Total number of students: 185 Total number of Faculty members: 5
Event Summary:	The events were successfully conducted on the scheduled days to achieve the above-mentioned objectives
Feedback (if applicable):	It was done as reflection writing in the foundation course logbook



Visit to Herbal Garden



Primary Healthcare Systems: Lecture

*[Handwritten Signature]*

Signature of event coordinator (NSS unit coordinator/Student council coordinator etc)

*[Handwritten Signature]*

Signature of Criterion V Coordinator/Incharge of the Institute

*[Handwritten Signature]*

Signature of Institute's IQAC Coordinator

**Coordinator**  
**IQAC**

**MGM Medical College & Hospital**  
Kamothe, Navi Mumbai - 410 209

*[Handwritten Signature]*

Signature of Head of Institute

**Dean**

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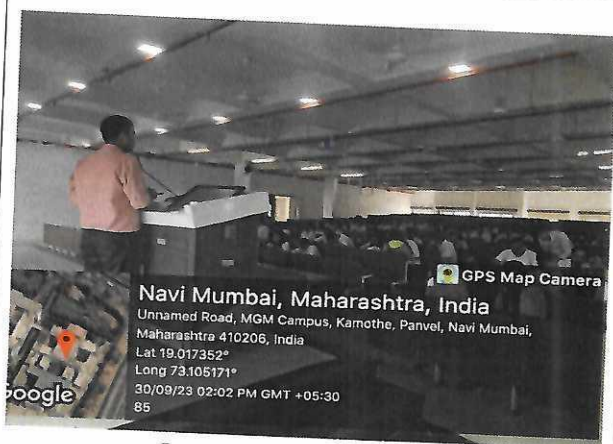


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DEPARTMENT OF BIOCHEMISTRY

Name of the Event:-**Personality Development**


Event Date:	4/9/23
Venue:	Lecture Hall 6, 5th Floor
Organized by:	Foundation Course Committee, BIOCHEMISTRY Dept
Objectives:	To teach the students the values of Personality development, namely: 1. Socializing 2. Professionalism 3. Altruistic behaviour
Number of Participants:	Total number of students:183 Total number of Faculty members: 2
Event Summary:	The above-mentioned objectives were achieved successfully.
Feedback :	Taken at the end




Lecture: Professionalism



Lecture: Altruistic Behaviour

  
 Signature of event coordinator (NSS unit coordinator/Student council coordinator etc)

  
 Signature of Criterion V Coordinator/In charge of the Institute

  
 Signature of Institute's IQAC Coordinator

  
 Signature of Head of Institute

**Coordinator**  
**IQAC**

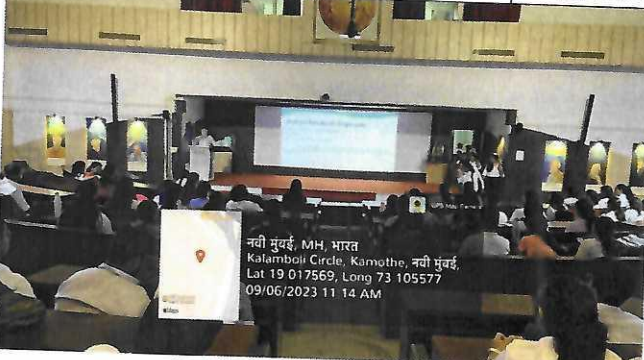

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**DEPARTMENT OF BIOCHEMISTRY**

<b>Foundation Course: Professional development</b>	
<b>Event Date:</b>	2/9/23, 6/9/23
<b>Venue:</b>	MGM Lecture Hall 5 & EMS Seminar Hall
<b>Organized by:</b>	Foundation Course Committee, BIOCHEMISTRY Dept
<b>Objectives:</b>	<ul style="list-style-type: none"> <li>To sensitize to the concept of Professionalism and Ethics.</li> <li>To understand that clinical competency, communication skills and sound ethical principles which are the foundation of professionalism.</li> <li>To educate students on how to respect the differently abled persons.</li> <li>To sensitize students to "learning" as a behavior and to the appropriate methods of learning.</li> </ul>
<b>Number of Participants:</b>	<b>Total number of students: 173</b> <b>Total number of Faculty members: 2</b>
<b>Event Summary:</b>	<p>Students freely interacted with their colleagues without discrimination towards anyone. Students were advised to work towards ensuring an Ethical Doctor-patient relationship &amp; maintain public trust in health system.</p> <p>Students were also educated on the principles of professional behavior with respect to clinical settings and faculty.</p>
<b>Feedback (if applicable):</b>	It was done as reflection writing in the foundation course logbook
 <p style="text-align: center;"><b>Lecture: Professionalism</b></p>	 <p style="text-align: center;"><b>Lecture: Professional behavior</b></p>
<p style="text-align: center;"><i>[Signature]</i></p> <p style="text-align: center;">Signature of event coordinator (NSS unit coordinator/Student council coordinator etc.)</p>	<p style="text-align: center;"><i>[Signature]</i></p> <p style="text-align: center;">Signature of Criterion V Coordinator/In charge of the Institute</p>
<p style="text-align: center;"><i>[Signature]</i></p> <p style="text-align: center;">Signature of Institute's IQAC Coordinator</p>	<p style="text-align: center;"><i>[Signature]</i></p> <p style="text-align: center;">Signature of Head of Institute</p>

**Coordinator**  
**IQAC**  
**MGM Medical College & Hospital**  
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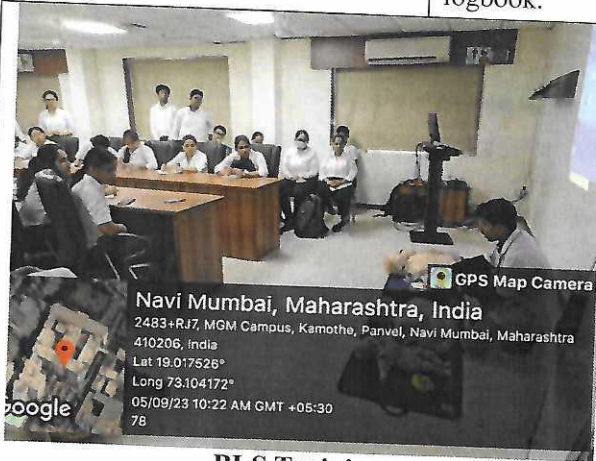
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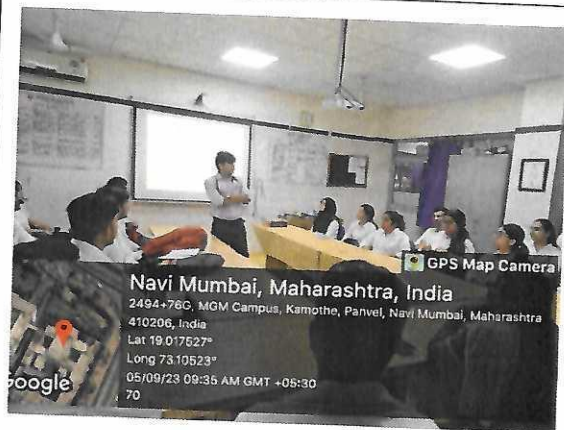
**DEPARTMENT OF BIOCHEMISTRY**

**Foundation Course : Employability skills development**


<b>Event Date:</b>	02/09/23, 04/09/23, 05/09/23, 06/09/23, 07/09/23
<b>Venue:</b>	Lecture Hall 5, 5 <sup>th</sup> Floor + Skills lab, MGM Hospital
<b>Organized by:</b>	Foundation Course Committee ,BIOCHEMISTRY Dept
<b>Objectives:</b>	To educate students on basic medical knowledge like: <ol style="list-style-type: none"> <li>1) BLS</li> <li>2) First Aid</li> <li>3) Library Resources</li> <li>4) Legal aspects of medicine</li> </ol>
<b>Number of Participants:</b>	<b>Total number of students: 192</b>
<b>Event Summary:</b>	<b>Total number of Faculty members: 4</b> The above mentioned objectives were achieved by conducting sessions on the above given topics carried out by clinical and non clinical faculty.
<b>Feedback (if applicable):</b>	It was done as reflection writing in the foundation course logbook.





**BLS Training**




**FIRST AID Training**

  
Signature of event coordinator (NSS unit coordinator/Student council coordinator etc)

  
Signature of Criterion V Coordinator/Incharge of the Institute

  
Signature of Institute's IQAC Coordinator

  
Signature of Head of Institute  
**Dean**

**Co-ordinator**  
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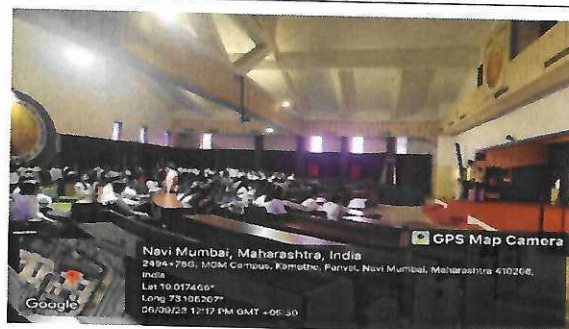
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**Name of the Event – Introduction to Medical Research**

<b>Event Date:</b>	6/9/23, 7/9/23
<b>Venue:</b>	5 <sup>th</sup> Floor Lecture hall and MGM Auditorium
<b>Organized by:</b>	Foundation Course Committee, BIOCHEMISTRY Dept
<b>Objectives:</b>	<ul style="list-style-type: none"> <li>To introduce the students to the basics of medical research</li> <li>To educate on the ethical aspects of conducting research</li> <li>To simplify the methodology of research and introduce students to the ICMR STS Programme</li> </ul>
<b>Number of Participants:</b>	Total number of students: 177 Total number of Faculty members: 2
<b>Event Summary:</b>	The events were successfully conducted on the scheduled days to achieve the above-mentioned objectives.
<b>Feedback (if applicable):</b>	It was done as reflection writing in the foundation course logbook



**Lecture: Basics of Research**



**Lecture: Ethics in Research**

Signature of event coordinator (NSS unit coordinator/Student council coordinator etc)

Signature of Criterion V Coordinator/Incharge of the Institute

Signature of Institute's IQAC Coordinator

Signature of Head of Institute

**Dean**

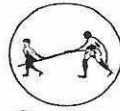
**Co-ordinator  
IQAC**

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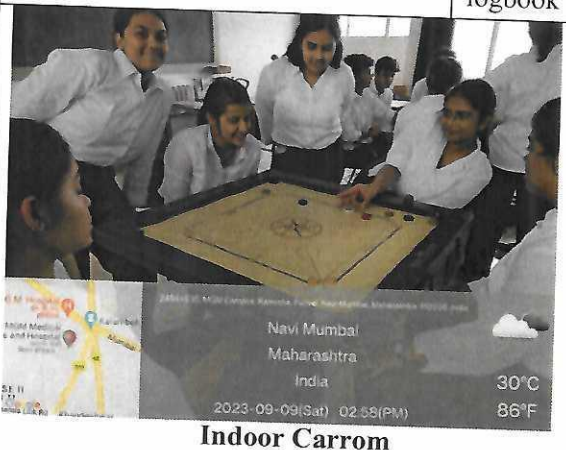
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**Name of the Event – Sports and Extra Curricular Activities**

<b>Event Date:</b>	02/09/23
<b>Venue:</b>	MGM Sports Room
<b>Organized by:</b>	Foundation Course Committee, BIOCHEMISTRY Dept
<b>Objectives:</b>	<ul style="list-style-type: none"> <li>To improve the mental &amp; physical health of the students</li> <li>To deal with depression &amp; anxiety amongst the students by physical activity</li> <li>To promote the overall development of students through extracurricular activities.</li> <li>To inculcate qualities such being a team player and sportsmanship.</li> </ul>
<b>Number of Participants:</b>	Total number of students: 191 200 students were divided into 7 small groups (A-G) Total number of Faculty members:1
<b>Event Summary:</b>	The events were successfully conducted on the scheduled days to achieve the above-mentioned objectives.
<b>Feedback (if applicable):</b>	It was done as reflection writing in the foundation course logbook



**Indoor Carrom**



**Indoor Chess**

*[Signature]*  
 Signature of event coordinator (NSS unit coordinator/Student council coordinator etc)

*[Signature]*  
 Signature of Criterion V Coordinator/Incharge of the Institute

*[Signature]*  
 Signature of Institute's IQAC Coordinator

*[Signature]*  
 Signature of Head of Institute

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**Name of the Event – Deekshaarambh: Inauguration & Induction**

<b>Event Date:</b>	01/09/23
<b>Venue:</b>	MGM Auditorium
<b>Organized by:</b>	Foundation Course Committee, BIOCHEMISTRY Dept
<b>Objectives:</b>	<ul style="list-style-type: none"> <li>To conduct an icebreaking session between the newly enrolled students.</li> <li>To introduce the students to the first-year faculties</li> <li>To conduct sensitization programme for the First-Year medical students</li> <li>To enable the students to socialize amongst each other.</li> </ul>
<b>Number of Participants:</b>	Total number of students: 198 Total number of Faculty members: 2
<b>Event Summary:</b>	The events were successfully conducted on the scheduled days to achieve the above-mentioned objectives.
<b>Feedback (if applicable):</b>	It was done as reflection writing in the foundation course logbook



Address by Dignitary



Lamp Lighting Ceremony

*[Signature]*  
 Signature of event coordinator (NSS unit coordinator/Student council coordinator etc)

*[Signature]*  
 Signature of Criterion-V Coordinator/Incharge of the Institute

*[Signature]*  
 Signature of Institute's IQAC Coordinator

*[Signature]*  
 Signature of Head of Institute

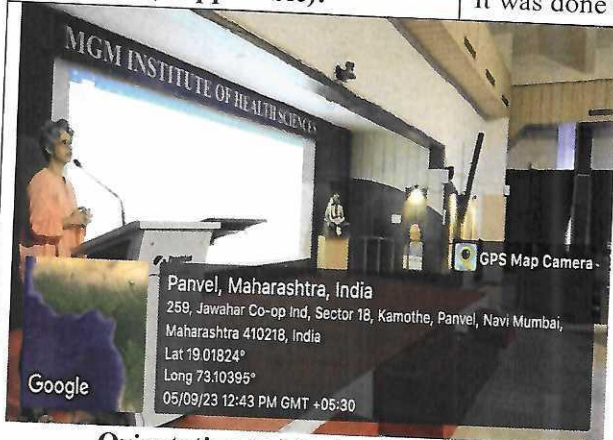
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**Name of the Event – Orientation to the MBBS course**

<b>Event Date:</b>	05/09/23
<b>Venue:</b>	Lecture Hall 6, 5th Floor
<b>Organized by:</b>	Foundation Course Committee, BIOCHEMISTRY Dept
<b>Objectives:</b>	<ul style="list-style-type: none"> <li>To orient the students to the medical college building including, the departments, and the mentorship programme.</li> <li>To orient the students to various facets of the CBME Curriculum as well as important committees such as IQAC and NSS</li> <li>To introduce the students to the Student Council</li> </ul>
<b>Number of Participants:</b>	Total number of students: 188 Total number of Faculty members: 1
<b>Event Summary:</b>	The events were successfully conducted on the scheduled days to achieve the above-mentioned objectives.
<b>Feedback (if applicable):</b>	It was done as reflection writing in the foundation course logbook



**Orientation to Mentorship Program**



**Hospital Visit**

*Gandhi*  
 Signature of event coordinator (NSS unit coordinator/Student council coordinator etc)

*S. S. Joshi*  
 Signature of Criterion V Coordinator/Incharge of the Institute

*A. S. Joshi*  
 Signature of Institute's IQAC Coordinator

*S. S. Joshi*  
 Signature of Head of Institute

**Co-ordinator**  
**IQAC**  
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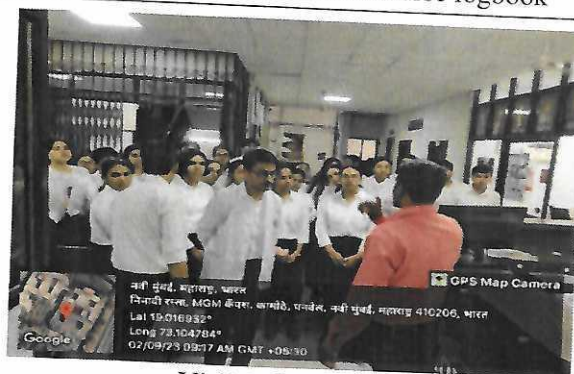
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**Name of the Event – Campus Orientation**

<b>Event Date:</b>	2/9/2023, 4/9/23, 5/9/23, 6/9/23, 7/9/23
<b>Venue:</b>	MGM Campus
<b>Organized by:</b>	Foundation Course Committee, BIOCHEMISTRY Dept
<b>Objectives:</b>	<ul style="list-style-type: none"> <li>To orient the students to the MGM Campus</li> <li>To enable the students to better understand community-based medicine and the Family Adoption Programme.</li> </ul>
<b>Number of Participants:</b>	Total number of students:170 200 students were divided into 7 small groups (A-G) Total number of Faculty members:4
<b>Event Summary:</b>	The events were successfully conducted on the scheduled days to achieve the above-mentioned objectives.
<b>Feedback (if applicable):</b>	It was done as reflection writing in the foundation course logbook



Visit To Hospital Lab



Visit to Library

*[Signature]*  
 Signature of event coordinator (NSS unit coordinator/Student council coordinator etc.)

*[Signature]*  
 Signature of Criterion V Coordinator/In charge of the Institute

*[Signature]*  
 Signature of Institute's IQAC Coordinator

*[Signature]*  
 Signature of Head of Institute

**Coordinator**  
**IQAC**  
**MGM Medical College & Hospital**  
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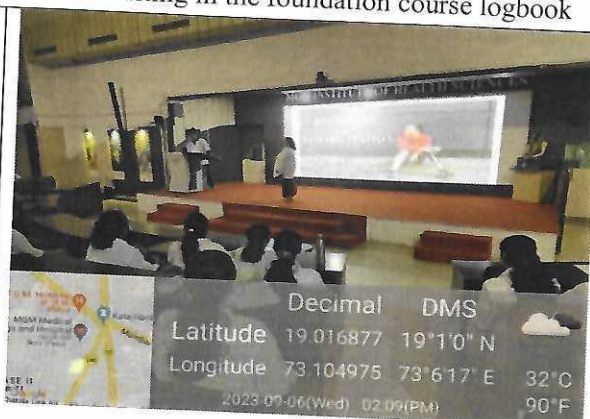
**Name of the Event – Holistic overview of Medical Care**

<b>Event Date:</b>	6/9/23
<b>Venue:</b>	Lecture Hall 6, 5th Floor
<b>Organized by:</b>	Foundation Course Committee ,BIOCHEMISTRY Dept
<b>Objectives:</b>	<ul style="list-style-type: none"> <li>To explore the principles of medical care, alternate healthcare systems and understand the roots of clinical practice</li> <li>To educate the students on the history and the legal aspects of modern medicine.</li> <li>To give the students an understanding on the methodology of medical record keeping and documentation</li> </ul>
<b>Number of Participants:</b>	Total number of students: 193 Total number of Faculty members: 6
<b>Event Summary:</b>	The events were successfully conducted on the scheduled days to achieve the above mentioned objectives.
<b>Feedback (if applicable):</b>	It was done as reflection writing in the foundation course logbook



**Lecture: Indian Medical Graduate**

*[Signature]*  
 Signature of event coordinator (NSS unit coordinator/Student council coordinator etc)



**Lecture: Disability and Rehabilitation**

*[Signature]*  
 Signature of Criterion V Coordinator/In charge of the Institute

*[Signature]*  
 Signature of Institute's IQAC Coordinator

**Co-ordinator**  
**IQAC**

**MGM Medical College & Hospital**  
 Kamothe, Navi Mumbai - 410 209.

*[Signature]*  
 Signature of Head of Institute

**Dean**  
**MGM Medical College & Hospital**  
 Kamothe, Navi Mumbai - 410 209

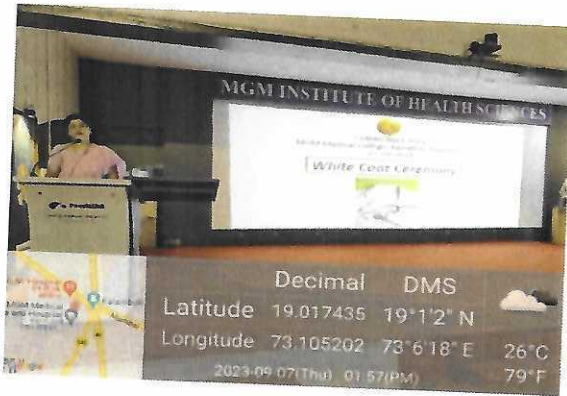
5.1.2 Detailed report of the Capacity enhancement programs and other skill development schemes



Mahatma Gandhi Mission's  
**MEDICAL COLLEGE**  
 Sector- 01, Kamothe, Navi Mumbai - 410 209.  
 Ph: 0227433404, 27437991, 27437992, Fax: (022) 27431094  
 E-mail: [mgmmcnb@gmail.com](mailto:mgmmcnb@gmail.com), Web: [www.mgmmcnm.edu.in](http://www.mgmmcnm.edu.in)

**Name of the Event:-White Coat Ceremony**


Event Date:	7/9/2023
Venue:	MGM Auditorium
Organized by:	Foundation Course Committee, BIOCHEMISTRY Dept
Objectives:	All the first MBBS students were conferred with their white coats by the honorable dignitaries, as well as educated about the significance of the White Coat.
Number of Participants:	Total number of students:200 Total number of Faculty members: Phase 1 Faculty
Event Summary:	The above-mentioned objectives were achieved successfully.
Feedback :	Taken at the end





White Coat Ceremony

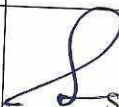


Oath taking Session

  
 Signature of event coordinator (NSS unit coordinator/Student council coordinator etc)

  
 Signature of Criterion V Coordinator/Incharge of the Institute

  
 Signature of Institute's IQAC Coordinator

  
 Signature of Head of Institute

**Co-ordinator**  
**IQAC**

**MGM Medical College & Hospital**  
 Kamothe, Navi Mumbai - 410 209.

**MGM Medical College & Hospital**  
 Kamothe, Navi Mumbai-410209



**Mahatma Gandhi Mission  
MEDICAL COLLEGE**  
Sector-1, Kamothe, Navi Mumbai - 410 209, India

**UG STUDENT RESEARCH CELL UNDER THE MEDICAL EDUCATION UNIT**



2

**Report of**

**“NEXUS 2024: ACADEMIC AND RESEARCH CONFERENCE”**

The Undergraduate Medical Conference of MGM Medical College, Kamothe, Navi Mumbai

held on 20th and 22nd April, 2024

**Ms. Sanaya Shah**  
(Head of Academics)

**Ms. Revaa Kovil**  
(Head of Logistics)

**Ms. Maryah Kondkari**  
(Head of Social Media)

**Ms. Parnika Joshi**  
(Head of Public Relations)

**Dr. Mrunal Pimparkar**  
Professor, Community Medicine  
& MEU Co-ordinator

**Co-ordinator**  
Medical Education Unit  
M.G.M. Medical College,  
Kamothe, Navi Mumbai-410209

**Dr GS Narshetty**  
Dean  
MGM Medical College,  
Kamothe, Navi Mumbai

MGM Medical College & Hospital  
Kamothe, Navi Mumbai-410209



*Mahatma Gandhi Mission*  
**MEDICAL COLLEGE**  
Sector-1, Kamothe, Navi Mumbai - 410 209, India

**UG STUDENT RESEARCH CELL UNDER THE MEDICAL EDUCATION UNIT**

**Date: 24/05/2024**

**“NEXUS 2024: ACADEMIC AND RESEARCH CONFERENCE”**

**The Undergraduate Medical Conference of MGM Medical College, Kamothe, Navi Mumbai  
held on 20th and 22nd April, 2024**

**INTRODUCTION:**

The UG Student Research Cell under the Medical Education Unit, MGM Medical College, Kamothe, Navi Mumbai conducted “Nexus: An Academic and Research Conference”, an Undergraduate intercollegiate Medical Conference open to students of all semesters. Fitting for its name, meaning a connection or link, Nexus 2024 served as a central point to bring together ideas and individuals from various backgrounds, creating a hub of collaboration, knowledge and innovation. Covering a diverse range of topics within healthcare, from research presentations to hands-on training for an introduction to intestinal surgery, from enlightening seminars to Medical device hackathons, the conference served as a platform to bridge the gap between Academia and practical Clinical experience.

**The programme details are as under:**

**Dates: 20th and 22nd April, 2024**

**Timings: 12:00 to 6:00 pm on both the days**

**Total number of Delegates: 290**



# The Organising Team



**DR. SHASHANK DALVI**  
HON. VICE-CHANCELLOR,  
MGMHS, NAVIMUMBAI



**DR. NITIN KADAM**  
PRO-VICE CHANCELLOR,  
MGMHS



**DR. SUDHIR KADAM**  
MEDICAL DIRECTOR



**DR. RAJESH GOEL**  
REGISTRAR,  
MGMHS



**DR. CHANDRAMANI PATHAK**  
DIRECTOR RESEARCH,  
MGMHS



**DR. G.S. NARSHETTY**  
DEAN,  
MGM MEDICAL COLLEGE



**DR. MAUNAL PIMPARKAR**  
CO-ORDINATOR,  
MEDICAL EDUCATION UNIT

## ACADEMIC



**SANAVA SHAH**

## LOGISTICS



**REVA KOVIL**

## SOCIAL MEDIA



**MARVAH KONDKARI**

## PUBLIC RELATIONS



**PARNIKA JOSHI**



**JENISHA SANGHANI**



**ADITI GOEN**



**DIVYASH NAGORI**



**SHREYA KAUSHAL**



**IBRAHIM PIRKHAN**



**SAAD PATEL**



**MANVI PORWAL**



**SAVALI PALANDE**

**Planning and execution of conference:** Dr Mrunal Pimparkar, Medical Education Unit Coordinator and students from UG Student Research Cell obtained permission to conduct “Nexus 2024- an Academic and Research Conference” for UG students. 4 committees namely - Academics, Logistics, Social Media and Public Relations were formed where there were organizing students from all semesters. Events and workshops were planned in consultation with respective Faculties, material and logistics were planned. Brochures, banners, certificates, trophies and other required material were designed and procured. Promotion was done in our college and other colleges, after which registration was opened. Minimum delegate fees were charged from participants.

**Programme Schedule:**

**Day 1: 20th April, 2024**

<b>EVENT</b>	<b>TIME</b>	<b>VENUE</b>	<b>NO. OF PARTICIPANTS</b>
<b>CODE KIDLET</b> THE PALS WORKSHOP	12:00-2:00 PM	SKILLS LAB, MGM HOSPITAL	40
<b>STITCHCRAFT</b> A SURGICAL SUTURING WORKSHOP	12:00-1:30 PM	SKILLS LAB, MGM HOSPITAL	30
<b>GUT KNOT</b> A BOWEL ANASTOMOSIS WORKSHOP	12:00-1:30 PM	SKILLS LAB, MGM HOSPITAL	12
<b>BEYOND THE BELLY:</b> A LAPAROSCOPY WORKSHOP	1:30-3:00 PM	SKILLS LAB, MGM HOSPITAL	16
<b>SEMINAR</b> KIDNEY TRANSPLANTATION- A CENTURY LONG SAGA	3:00-3:30 PM	LECTURE HALL 3, MGM COLLEGE	49
<b>RADIORIDDLES</b> DIAGNOSTIC QUIZ	3:30-5:30 PM	LECTURE HALL 2, MGM COLLEGE	16
<b>INVICTUS</b> MEDICAL DEBATE	3:30-5:30 PM	SEMINAR ROOM, MGM HOSPITAL	8
<b>BACK TO BASICS</b> PRE AND PARA CLINICAL QUIZ	3:30-5:30 PM	LECTURE HALL 3, MGM COLLEGE	27

Day 2: 22nd April, 2024

<b>EVENT</b>	<b>TIME</b>	<b>VENUE</b>	<b>NO. OF PARTICIPANT</b>
<b>CRITICARE</b> THE EMERGENCY MEDICINE WORKSHOP	12:00-3:00 PM	SKILLS LAB, MGM HOSPITAL	64
<b>AID ZONE</b> THE MEDICAL MANAGEMENT WORKSHOP	12:00-3:00 PM	SKILLS LAB, MGM HOSPITAL	30
<b>MEDSTEIN</b> MEDICAL HACKATHON	1:00-3:00 PM	LECTURE HALL 2, MGM COLLEGE	11
<b>MEDICAMENTUM</b> THE PAPER PRESENTATION	1:00-3:00 PM	SEMINAR ROOM, MGM HOSPITAL	3
<b>SEMINAR</b> ADVANCES IN CARDIOLOGY	3:30-4:00 PM	LECTURE HALL 2, MGM COLLEGE	49
<b>DIAGNOQUEST</b> AN OPD CHALLENGE	4:00-6:00 PM	LECTURE HALL 3, MGM COLLEGE	24
<b>THE GREATEST SHOWMAN</b> THE POSTER PRESENTATION	4:00-6:00 PM	MEU ROOM, MGM COLLEGE	8

## Day 1 (20/04/2024) of Conference:

The first day (20/04/2024) of the Conference started with Registration of delegates, followed by the **Inauguration ceremony** in the presence of Honorable Medical Director- Dr Sudhir Kadam Sir, Director of Research- Dr Chandramani Pathak, Dean MGM Medical College Kamothe- Dr G.S. Narshetty, Medical Education Unit Co-ordinator- Dr Mrunal Pimparkar, Prof & HOD, General Surgery and Director Skills Lab- Dr. Sameer Kadam and Prof & HOD, Medicine- Dr. Jaishree Ghanekar. After a welcome address and brief introduction to MGM and Nexus, we began with a prayer followed by lighting of the Diya and speeches by all our distinguished dignitaries on Dias. Dr. Sudhir Kadam Sir did the ribbon cutting and declared the Conference open.

## **Inauguration Ceremony**





**Honorable Medical Director, Dr. Sudhir Kadam Sir, Dr G.S. Narshetty and Dr Chandramani Pathak during Lighting Ceremony of NEXUS 2024 Conference held on 20<sup>th</sup> April, 2024.**



Navi Mumbai, MH, India  
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 04/20/2024 11:59 AM GMT+05:30  
 Note : Captured by GPS Map Camera



Navi Mumbai, MH, India  
 Kamothe, Navi Mumbai, 410209, MH, India  
 Lat 19.016963, Long 73.105293  
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 Note : Captured by GPS Map Camera

**Dr Sameer Kadam, Prof & Head of Department of Surgery lights the diya during Inauguration Ceremony of Nexus.**

**Organising students-Sanaya Shah, Head of Academics and Maryah Kondkari, Head of Social Media during the Diya Lighting Ceremony.**



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 Kamothe, Navi Mumbai, 410209, MH, India  
 Lat 19.016949, Long 73.105150  
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 Note : Captured by GPS Map Camera



**Honorable Medical Director, Dr Sudhir Kadam Sir addressing the Audience.**



**Director of Research,  
Dr Chandramani  
Pathak Sir addressing  
the Audience.**



**Respected Dean Sir, Dr G.S. Narshetty  
addressing the delegates during the  
Inaugural Ceremony.**



**Dr Mrunal Pimparkar, Medical Education  
Unit Co-Ordinator addressing the  
delegates during the Inaugural Ceremony.**





**Dr Sameer Kadam, Prof & Head, General Surgery and Dr Jaishree Ghanekar, Prof & Head, General Medicine delivering the Welcome address during the Inaugural ceremony.**



**MBBS Student Revaa Kovil, Head of Logistics, delivering the Welcome address during Inaugration ceremony of Nexus.**

**The following events and workshops succeeded this ceremony on Day 1 (20/04/2024):**

**1.Code Kidlet: A Pediatric advanced life support workshop** conducted by Dr Jeetendra Gavhane, Dr Priyanka Amonkar and Dr Suhas Kharchewas a transformative workshop where 40 participants delved into advanced life-saving techniques for infants and children. Divided into two stations, Basic Life Support (BLS) and Pediatric Airway Management, attendees engaged in hands-on activities with lifelike models, augmented by real-time feedback from a connected app which ensured precision in their techniques. Covering basic CPR, airway management, emergency care, intubation, and the crucial ABCs of emergency response: Airway, Breathing, and Circulation. This interactive approach not only deepened understanding but also honed proficiency in pediatric emergency care, equipping participants with essential skills to confidently save young lives.

**Time: 12:00-2:00 pm**

**Venue: Skills Lab, MGM Hospital, Kamothe, Navi Mumbai No.**

**of participants- 39**



**Dr Suhas Kharche demonstrating Intubation on a mannequin during Code Kidlet, The Pediatric Advanced Life Support Workshop held on 20<sup>th</sup> April 2024.**

## Code Kidlet - A Pediatric advanced life support workshop



### Delegates practice Airway Management under the guidance of Dr Suhas Kharche



### Dr Jeetendra Gavhane, demonstrates Basic Life Support (BLS) in Station 2 of Code Kidlet.

**StitchCraft: A surgical suturing workshop conducted by Dr Sameer Kadam** provided medical students with hands-on experience in debridement and suturing techniques on live tissues, offering a practical and immersive learning opportunity. By simulating real surgical scenarios, students gained valuable skills and confidence in wound management, enhancing their ability to provide effective patient care in the future. Covering wound debridement on chicken legs and suturing including simple sutures, horizontal and vertical mattress sutures on porcine skin ensured that each participant got to take home not just a new skill, but also a one-of-a-kind unique experience.

**Time: 12:00-1:30 pm      Venue: Skills Lab, MGM Hospital, Kamothe, Navi Mumbai**

**No. of participants-30**



**Delegates having hands-on-training in the StitchCraft, the Surgical Suturing Workshop on 20th April 2024.**

## StitchCraft- A surgical suturing workshop



**Delegates practicing wound debridement on chicken legs and suturing on porcine skin under the supervision of Dept of General Surgery**



**Dr Sameer Kadam, Prof & Head, General Surgery giving Orientation to students about surgical suturing during the Workshop.**

**Gut Knot: A Bowel Anastomosis Workshop** conducted by Dr Sameer Kadam and the Department of General Surgery was an introduction to the field of intestinal surgery. The participants were taught how to suture on pig bowel tissue. They were shown videos and live demos for the same. The teachers from the Surgery dept made small groups which gave each and every one personal attention. Overall, the event was a great success and every delegate learnt a new skill.

**Time: 12:00-1:30 pm**

**Venue: Skills Lab, MGM Hospital, Kamothe, Navi Mumbai**

**No. of participants- 12**



**Delegates get oriented to the field of Intestinal Surgery during Gut Knot, the Bowel Anastomosis Workshop conducted by Department of Surgery on 20<sup>th</sup> April 2024.**

## Gut Knot Workshop



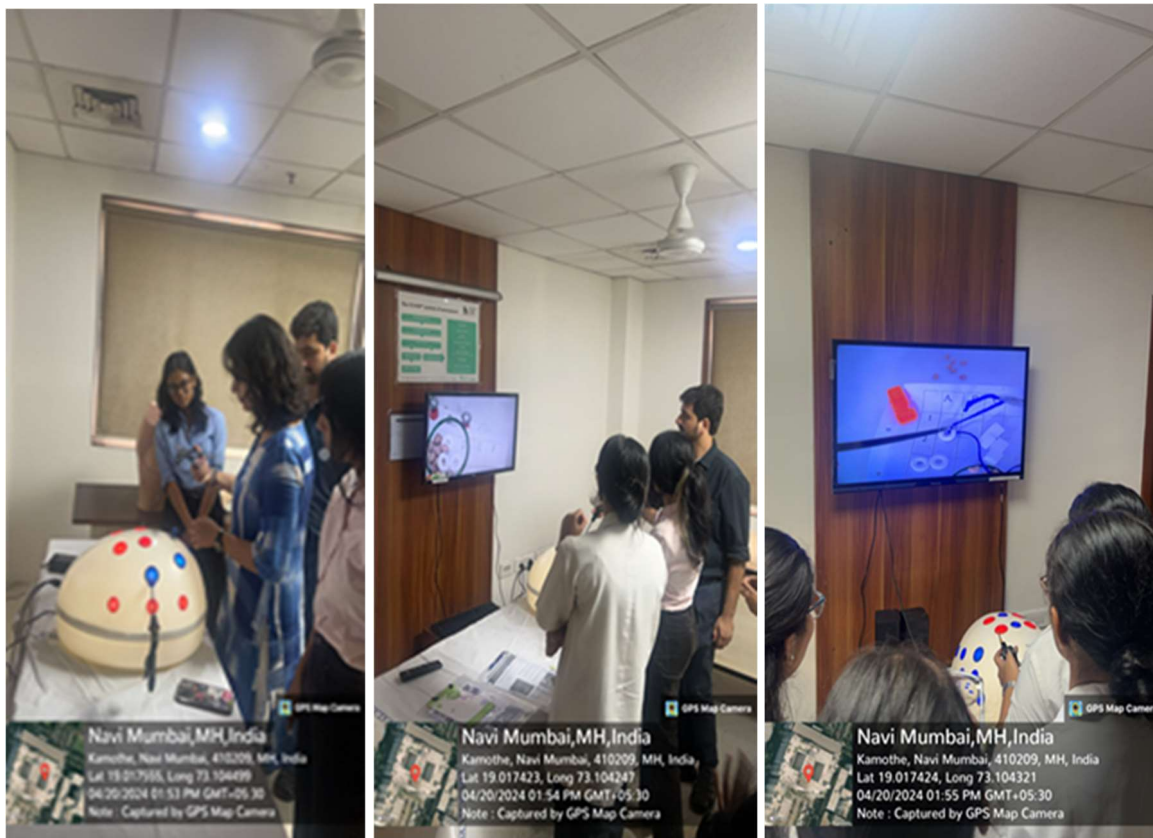
Faculties from Department of General Surgery giving hands-on-training to delegates during Gut Knot Workshop

**Beyond The Belly: A Laptastic Introduction to Laparoscopy”** -conducted by Dr Sameer Kadam with the help of residents from the Department of Surgery provided the participants with the opportunity to gain hands-on experience in the field of laparoscopy, utilizing a laparoscopic simulator. They were assigned three tasks: stacking sugar cubes, placing peanuts in a cup, and threading string through a polo, aimed at helping aspiring surgeons gain the skill of hand-eye coordination, which is imperative for mastering laparoscopic techniques. Through expert-led demonstrations and interactive sessions, attendees acquired practical skills in laparoscopic procedures, including instrumentation and navigation. The workshop provided a platform for sharing best practices and discussing emerging trends in the field, fostering collaboration among surgeons and medical students. Overall, the workshop served as a valuable platform for continuous learning and skill development in the realm of minimally invasive surgery.

**Time: 1:30 pm-3:00 pm**

**Venue: Skills Lab, MGM Hospital, Kamothe, Navi Mumbai**

**No. of participants-16**



**Delegates practice hand eye coordination by stacking sugar cubes, placing peanuts in a cup, and threading string through a polo during Beyond The Bell, A Laptastic Introduction to Laparoscopy Workshop.**

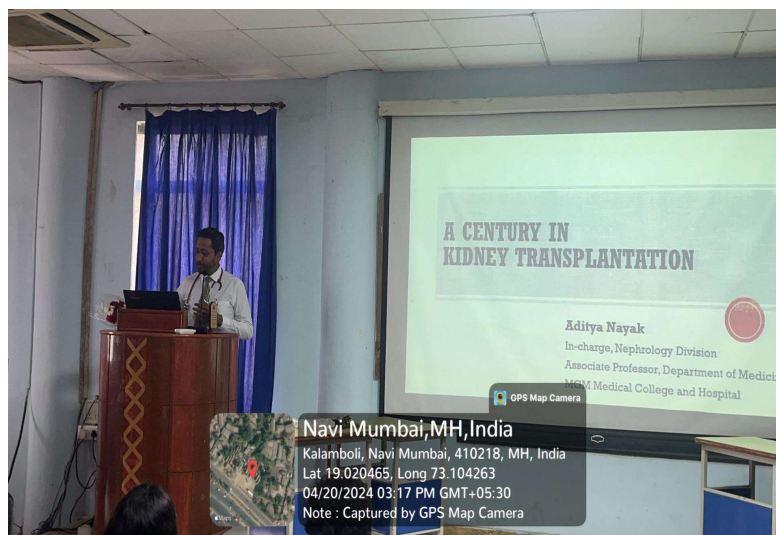


**A century In Kidney Transplantation- Seminar:** Dr. Aditya Naik, a seasoned Nephrologist with 14 years of clinical expertise, delivered an illuminating seminar on advancements in Kidney transplantation. Drawing from his extensive experience, Dr. Naik elucidated groundbreaking developments in the field, offering insights into innovative techniques and emerging trends. Attendees gained valuable knowledge on the latest approaches to donor selection, surgical procedures, immunosuppressive therapies, and post-transplant care, enriching their understanding of contemporary practices in renal transplantation. Dr. Naik's expertise and engaging presentation style ensured a comprehensive exploration of this vital aspect of nephrology.

**Time: 3:00-3:30 pm**

**Venue: Seminar room, 2nd floor, MGM Hospital, Kamothe, Navi Mumbai**

**No. of participants-49**



**Dr Aditya Nayak conducts a seminar on Kidney Transplantation: A century long saga.**

**Back to Basics: A Pre and para clinical quiz”** was conducted under the supervised guidance of Dr Manisha Tambekar, Dr Santosh Gawali and Dr Snigda Misra. In the "Back to Basics" quiz competition, teams with participants from different years engaged in intense battles through rounds packed with challenging questions, putting their knowledge and quick thinking on full display. Rounds, ranging from fundamental basics to clinical scenarios, Pictionary challenges, audiovisual rounds and culminating in a thrilling lightning questions round and spanning all the subjects of the first two years such as anatomy, biochemistry, pharmacology, and microbiology, the competition kept both participants and onlookers captivated. Participants also had the chance to utilize lifelines, including seeking expert advice from judges, adding an extra layer of excitement to the proceedings. Ultimately, the event underscored the invaluable qualities of teamwork, intellect, and poise under pressure.

**Time: 3:30-5:30 pm    Venue: Lecture hall 3, MGM Medical College, Kamothe, Navi Mumbai**

**No. of participants- 27 (9 teams)**



**Dr Santosh Gawali and Dr Manisha Tambekar receive felicitation for judging Back to Basics: A Pre and para clinical quiz conducted on 20<sup>th</sup> April 2024.**

## Back to Basics: A Pre and para clinical quiz



**Teams with participants from different years engaged in intense battles through rounds packed with challenging questions.**



**Judges Dr. Manisha Tambekar, Dr Santosh Gawali and Dr Snigda Misra giving awards to the winning team**

**Invictus: A Medical Debate-** was an inter college debate competition that saw a battle of words with contestants launching razor sharp witty arguments ranging from telemedicine in everyday life, professional surrogacy and the future of online medical education.

These topics were meticulously crafted by the hosts thus giving each contestant a chance to express themselves to the fullest, and the event being judged by the keen eyes of Dr Amol Madave, Dr Rita Khadkikar and Dr Deepanjana Das guided each participant along a road where they could simultaneously learn and better themselves.

**Time: 3:30-5:30 pm Venue: Seminar room, MGM Hospital, Kamothe, Navi Mumbai**

**No. of participants- 8 (4 teams)**



**Delegates engage in witty arguments during Invictus, the Medical debate conducted on 20<sup>th</sup> April 2024.**

## Invictus: A Medical Debate



The topics for various rounds ranged from telemedicine in everyday life, professional surrogacy and the future of online medical education.



The Judges Dr Amol Madave, Dr Rita Khadkikar and Dr Deepanjana Das addressing the delegates at the Medical Debate

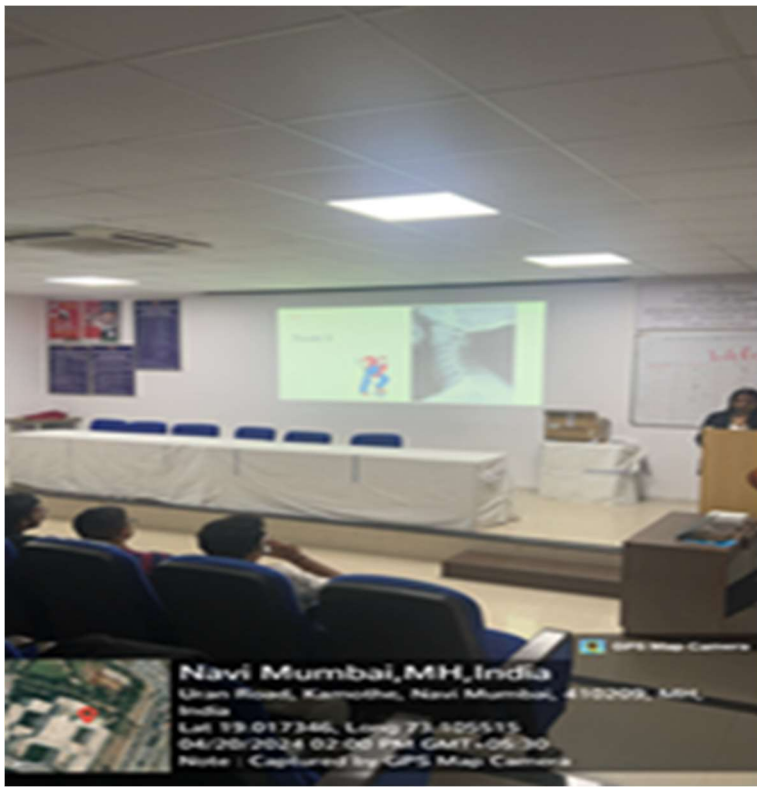
**RadioRiddles: A radiology quiz** was an intercollege quiz competition with exciting rounds encompassing all major aspects of radiology. The participants ranged from 2nd years to interns of MBBS from various colleges and was judged by Dr. Jai Thakker. It exclusively centered on the diverse radiology aspects of medicine, encompassing riddles and questions on topics such as anatomical structures on CT scans, X-rays and Case based radiological investigations. The event featured a challenging rapid fire round designed to stimulate participants' minds and test their knowledge. The competition was intense, with the first two teams neck and neck in the race for victory. Overall, Radioriddles was a resounding success, offering participants a unique and engaging experience in the field of radiology.

**Time: 3:30-5:30 pm Venue: Lecture hall 2 , MGM Hospital, Kamothe, Navi Mumbai**

**No. of participants- 16 ( 4 teams )**



**Dr. Jai Thakker, from Department of Radiology (judge for the event) giving awards to the winning team.**



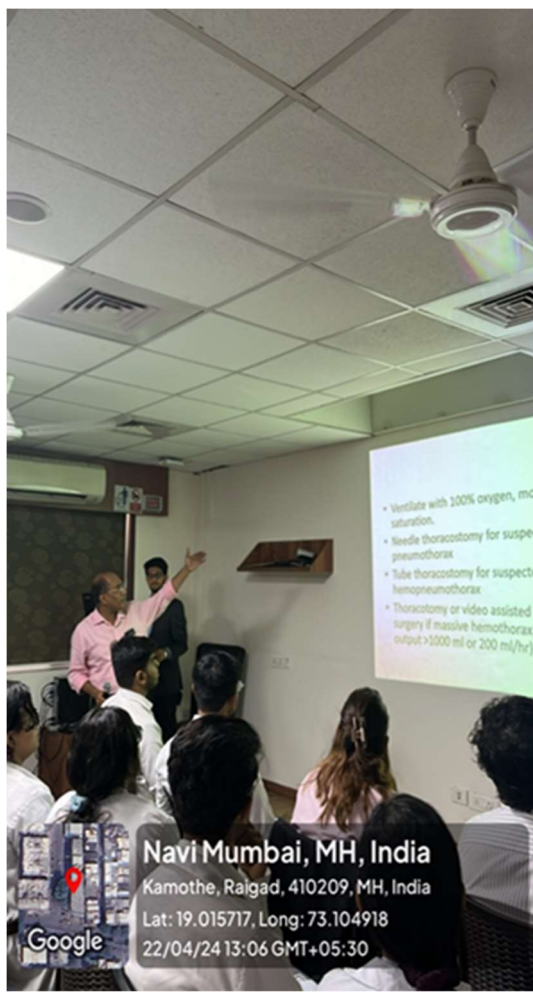
**RadioRiddles: A radiology quiz was an intercollege quiz competition with exciting rounds encompassing all major aspects of Radiology conducted on 20<sup>th</sup> April 2024.**

## Day 2 (22/04/2024) of Conference:

**CritiCare: An Emergency Medicine workshop** was a pivotal workshop, conducted by Dr.Dattatray Bhusare and the Department of Emergency Medicine. Delving into the fundamentals of EMS, participants were systematically guided through the essential "ABCD" principles. The dynamic format of the workshop involved attendees being seamlessly rotated among four stations, each dedicated to Airway, Breathing, Circulation, and Disability. This immersive experience fostered an environment of robust learning and engagement. As we reflect on its success, anticipation builds for the prospect of expanding upon this initiative next year, introducing more innovative content.

**Time: 12:00-3:00 pm    Venue: Skills Lab, MGM Hospital, Kamothe, Navi Mumbai**

**No. of participants- 64**



**CritiCare: An Emergency Medicine workshop was conducted by Dr. Dattatray Bhusare and the Department of Emergency Medicine on 22<sup>nd</sup> April 2024.**



## CritiCare: An Emergency Medicine workshop



Delegates practice on mannequins during Emergency Medicine workshop conducted on 22<sup>nd</sup> April 2024



Dr Sagar Sinha demonstrating Airway securement to the delegates.



Delegates practice logroll during one of the stations of Emergency Medicine workshop.

**AidZone: A medical management workshop** conducted by Dr. Prashant Gaikwad, Dr. Supriya Jatal and Dr. Rahul Jankar under the guidance of Dr Jaishree Ghanekar explored the intricacies of medicine including blood sugar analysis, hemodialysis and stroke management thus helping us to provide timely care for the patients in distress and preventing their condition from worsening.

The participants learnt methods to tackle each of these separately in intriguing concise 25 min stations each faultless and immaculate but at the same time simple enough to execute in the real world.

**Time: 12:00-3:00 pm**

**Venue: Skills Lab, MGM Hospital, Kamothe, Navi Mumbai**

**No. of participants- 30**



**AidZone: A Medical management workshop was conducted on 22<sup>nd</sup> April 2024 where delegates learnt to manage Medical emergencies such as stroke.**

## AidZone: A Medical management workshop



**Dr Rahul Jankar, Department of General Medicine teaching students during Aid Zone, The Medical Management Workshop.**

**Medicamentum: A Paper presentation** welcomed three esteemed judges, Dr. Preety Deshpande, Dr. Ashlesha Tawade and Dr Ipseeta Ray set the stage for a spectacle of brilliance. As presentations unfolded and ideas soared, with the pioneering research of three budding scientists, culminating in the triumphant win of Miss Maryah Kondkari in first place, closely followed by Miss Neha Gawde in second. Applause filled the air as winners and judges were honored, closing with heartfelt thanks for all who made the event unforgettable.

**Time: 1:00-3:00 pm**

**Venue: Seminar room, 2nd floor, MGM Hospital, Kamothe, Navi Mumbai No. of participants- 3**



**Delegates present their research during Medicamentum, the Paper presentation competition conducted on 22<sup>nd</sup> April 2024.**

**Med-stein: A Medical Hackathon** was brought alive keeping in mind that innovation is not born simply out of a void but out of a need to heal chaos. In this spirit, the esteemed judges Dr Yogesh Patil, Dr Sanjay Doke and Dr Ganesh Nair came together to hear the voices of the scientists of tomorrow. The medical hackathon was an exhilarating event where 4 teams from medicine and its allied sciences presented simply exceptional medical innovations that overcame a gap or shortcoming in Indian healthcare and were relevant in Indian epidemiology. The teams pitched their unique innovations, focusing on scientific rationale, relevance, feasibility, business model, etc and thoroughly impressed the team, judges and the audience alike.

**Time: 1:00-3:00 pm**

**Venue: Lecture hall 2, MGM College, Kamothe, Navi Mumbai**

**No. of participants- 11**



**Med-stein: A Medical Hackathon was an innovation competition where students from medical and paramedical fields came together to present their groundbreaking ideas.**



**Med-stein: A Medical Hackathon saw participation from medical and paramedical students alike.**



**Dr Ganesh Nair, one of the judges for the event gets facilitated by the students.**

**Seminar on “Advancements in Cardiology”:** Renowned in both pediatrics and cardiology, Dr. Shilpa Kadam shared her 21 years of expertise in a seminar focusing on the latest advancements in cardiac care. Drawing from her extensive educational background and clinical experience, Dr. Kadam provided attendees with an insightful exploration of cutting-edge developments in the field. From innovative diagnostic tools to groundbreaking therapeutic approaches, participants gained valuable insights into enhancing patient care and staying abreast of evolving trends in cardiology.

**Time: 3:30-4:00 pm**

**Venue: Lecture hall 2, MGM College, Kamothe, Navi Mumbai**

**No. of participants- 52**



**Dr Shilpa Kadam shares her years of expertise in a seminar focusing on the latest Advancements in cardiac care.**

**“The Greatest Showman: A Poster presentation”** got together the clinical and research aspects of the medical field, combining together the two pillars of health. Participants had to present a visually compelling poster about a case report or a research paper. The event was judged by esteemed judges Dr Mrunal Pimparkar, Dr Bageshree Seth, Dr Anjali Sabnis and Dr Vipul Bothara who gave each individual detailed opinions and questions. This competition has helped not just the participants being more confident in their speaking skills and have gotten the chance to improve their work. It has helped us team members by giving an insight into the workings of organizing and helped us highlight the importance of research in medical education.

**Time: 4:00-6:00 pm    No. of participants- 8**

**Venue: Medical Education Unit Room, MGM College, Kamothe, Navi Mumbai**



**Dr Mrunal Pimparkar, Dr Bageshree Seth, Dr Anjali Sabnis and Dr Vipul Bothara were the judges for the event.**



## The Greatest Showman: A Poster presentation



**Judges- Dr Mrunal Pimparkar, Dr Bageshree Seth, Dr Anjali Sabnis  
and Dr Vipul Bothara judging the Poster presentation at the  
Conference**



**Judges- Dr Mrunal Pimparkar, Dr Bageshree Seth, Dr Anjali Sabnis and Dr Vipul Bothara giving prizes to the winners of the poster presentation competition**



Navi Mumbai, MH, India  
Kamothe, Navi Mumbai, 410209, MH, India  
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Note : Captured by GPS Map Camera



Navi Mumbai, MH, India  
Kamothe, Navi Mumbai, 410209, MH, India  
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Note : Captured by GPS Map Camera



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Kamothe, Navi Mumbai, 410209, MH, India  
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Note : Captured by GPS Map Camera

**Delegates presenting  
their Research findings  
at the poster  
competition**

**DiagnoQuest: An OPD Challenge** Diagnoquest was a OPD simulation challenge where the contestants had to pick clues from cases, investigation, acts and examinations to reach the diagnosis. 12 teams participated which made the event competitive. There were 4 rounds each with a different twist adding excitement and tension to the quiz. Our judges Dr Badal Taori and Dr Mayur Garg added a rapid fire round which made the game more lively and enthusiastic.

**Time: 4:00-6:00 pm**

**Venue: Lecture hall 3, MGM College, Kamothe, Navi Mumbai**

**No. of participants- 24**





**Students take part in DiagnoQuest: An OPD Challenge conducted on 22<sup>nd</sup> April 2024.**

### DiagnoQuest: An OPD Challenge



**Judges Dr Badal Taori and Dr Mayur Garg giving prizes to winning team**

## List of Winners of various events held during Nexus Conference

Date of competition	Competition	Total no. of Participants	Prize Winners
20/04/2024	Radio Riddles- Radiology Quiz	16	<ul style="list-style-type: none"> <li>● <b>First Prize</b> Yash Varharde Debayam Bannerjee Harsh Marathe Junaid Shaikh (Seth GSMC)</li>   <li>● <b>Second Prize</b> Aariya Ramanujar Aavishkar Sawant Salim Kapdi Pratap Thombare (MGM Medical College Kamothe)</li> </ul>
20/04/2024	Invictus- Medical Debate	8	<ul style="list-style-type: none"> <li>● <b>First Prize</b> Natasha Sadhana Vishakha Pisharody (TNMC Nair)</li>   <li>● <b>Second Prize</b> Yashvi Shah Sameeksha Sarkar (MGM Medical College Kamothe)</li>   <li>● <b>Best Speaker</b> Sindhu Sadanand (MGM Medical College Kamothe)</li> </ul>
20/04/2024	Back To Basics- Pre and ParaClinical Quiz	27	<ul style="list-style-type: none"> <li>● <b>First Prize</b> Advait Dherange Rashi Banerjee Yash Dandekar (MGM Medical College Kamothe)</li>   <li>● <b>Second Prize</b> Devansh Jain Divyash Nagori Anusha Badarinath (MGM Medical College Kamothe)</li> </ul>

21/04/2024	MedStein- Medical Ideathon	11	<ul style="list-style-type: none"> <li>● <b>First Prize</b> Collin Tharakan Maryah Kondkari Sanaya Shah (MGM Medical College Kamothe)</li> <li>● <b>Second Prize</b> Nandini Suneja Sandipan Sinha Mansi Dhadheech (MGM Medical College Kamothe)</li> </ul>
21/04/2024	Medicamentum- The Paper Presentation	3	<ul style="list-style-type: none"> <li>● <b>First Prize</b> Maryah Kondkari (MGM Medical College Kamothe)</li> <li>● <b>Second Prize</b> Neha Gawade (MGM Medical College Kamothe)</li> </ul>
21/04/2024	The Greatest Showman- The Poster Presentation Competition	8	<ul style="list-style-type: none"> <li>● <b>First Prize</b> Dhey Mishra (Seth GSMC)</li> <li>● <b>Second Prize</b> Siddhant Palkar (KJ Somaya Medical College)</li> </ul>
21/04/2024	DiagnoQuest: An OPD Challenge	24	<ul style="list-style-type: none"> <li>● <b>First Prize</b> Khushbu Agrawal Anoushka Sehgal (MGM Medical College Kamothe)</li> <li>● <b>Second Prize</b> Jhanvi Nair Pratiksha Pathare (MGM Medical College Kamothe)</li> </ul>

## Conclusion:

The UG Academic Conference was conducted successfully on 20<sup>th</sup> and 22<sup>nd</sup> April 2024, 290 delegates from various colleges across Mumbai and Navi Mumbai participated in the Conference. The delegates appreciated all the sessions and workshops and found them interactive and informative.



**Ms. Sanaya Shah**  
(Head of Academics)



**Ms. Revaa Kovil**  
(Head of Logistics)



**Ms. Maryah Kondkari**  
(Head of Social Media)



**Ms. Parnika Joshi**  
(Head of Public Relations)



**Dr. Mrunal Pimparkar**  
Professor, Community Medicine  
& MEU Co-ordinator

**Co-ordinator**  
Medical Education Unit  
M.G.M. Medical College,  
Kamothe, Navi Mumbai-410209



**Dr. G.S. Narshetty**  
Dean  
MGM Medical College,  
Kamothe, Navi Mumbai



**Dean**  
MGM Medical College & Hospital  
Kamothe, Navi Mumbai-410209





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Tel no – 022/27433404, 27437904

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## **MEDICAL EDUCATION UNIT**

Date: 25/9/2023

**Report of PG Orientation Programme for MD/MS students (Admitted batch 2023-2024)  
conducted on 18/9/2023,  
by Medical Education Unit, MGM Medical College, Navi-Mumbai**

The Medical Education Unit conducted PG Orientation Programme for MD/MS students (Admitted batch 2023-2024) on 18/9/2023.

The programme details are as under:

**Date of PG Orientation programme: 18/9/2023**

**Timings:** From 2.30 PM to 5.00 PM

**Venue:** Lecture Hall 2, Ground floor, MGM Medical College building, Kamothe, Navi Mumbai.

**Total number of PG students (MD/MS batch 2023-2024) attended: 53**

**Total number of Teaching faculties attended: 12.**

**Planning and execution of PG Orientation Programme for MD/MS (Batch 2023-2024) students:**

The Medical Education Unit was given the responsibility to conduct the PG Orientation Programme for MD/MS (batch 2023-2024) students on 18/9/2023. A list of PG students who took admission for MD/MS course was obtained from Dean office. The PG students were informed about the date and venue of PG Orientation programme. A circular was sent to all HODs of PG depts to attend the Orientation programme along with Senior Professors and PG Guides. Also MGMIHS University officials, Hospital Director, Research Director, MEU Coordinator and other members, IQAC Coordinator, NABL Incharge, NABH Incharge were invited to participate in the PG Orientation

program. Necessary arrangements like seating arrangement of PG students, Faculties, AV Aids, refreshments etc was made.

**PG Orientation Programme for MD/MS (Admitted batch 2023-2024) students held on 18/9/2023:**

The PG Orientation Programme for MD/MS (Admitted batch 2023-2024) students started with a welcome/ opening remarks by Dr. Mrunal Pimparkar, Professor, Community Medicine & MEU Co-ordinator. Lamp lighting was done by dignitaries and two top ranking PG students.

The following dignitaries & Teaching faculties addressed the PG students:

- 1) Dr. Mrunal Pimparkar, Professor, Community Medicine & MEU Co-ordinator welcomed the audience and gave an overview of the Orientation programme.
- 2) Dr. G. S. Narshetty, Dean, MGM Medical College, Kamothe welcomed the PG students. He gave an overview of the Institute, academics, research, roles and responsibilities of PGs, teaching, infrastructure, facilities available etc.
- 3) Dr. Kuldeep Salgotra, Hospital Director, MGM Hospital, Kamothe briefed about the hospital infrastructure, facilities, and code of conduct.
- 4) Dr. Rahul Peddavar, Medical Superintendent, MGM Hospital, Kamothe, briefed the PG students about the roles and responsibilities of PGs while working in hospital etc.
- 5) Following HODs and Senior Professors of various depts addressed the PGs and briefed them about respective Department infrastructure, working schedule and pattern, activities, code of conduct, roles and responsibilities of PGs, District Residency Programme, Research etc:
  - a) Dr. Sameer Kadam, Professor & HOD, General Surgery
  - b) Dr. Bageshree Seth, Professor, Paediatrics
  - c) Dr. Sushil Kumar, Professor & HOD, OBGY
  - d) Dr. Rahul Kadam, Professor & HOD, Orthopaedics
  - e) Dr. D.B. Bhusare, Professor & HOD, Emergency Medicine
  - f) Dr. Shilpi Sahu, Professor, Pathology
  - g) Dr. Pankaj Patil, Professor, Family Medicine
  - h) Dr. Kalpana Rajivkumar , Professor & HOD, ENT
  - i) Dr. Bharat Dhareshwar, Professor & HOD, Geriatric Medicine
  - j) Dr. Darpan Kaur, Professor, Psychiatry

- k) Dr. Prasad Waingankar, Professor & HOD, Community Medicine
- l) Dr. Prakash Khandelwal, Professor & HOD, Pharmacology
- m) Dr. Ujwala Maheshwari, Professor, Pathology and Incharge, MGM Central Laboratory  
briefed about NABL, laboratory facilities etc.

This was followed by interaction with students. PG Students expressed their happiness about seeking admission in MGM and expressing their expectations and responsibilities. The PG students enthusiastically participated in the Orientation programme and found it interesting, informative and interactive.

The Vote of thanks was delivered by Dr. Mrunal Pimparkar, Professor, Community Medicine & MEU Coordinator, MGM Medical College, Navi Mumbai.



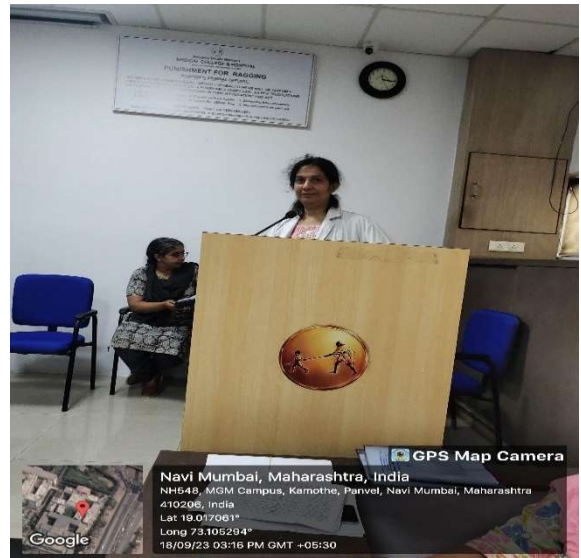
**Dr. Mrunal Pimparkar, Professor, Community Medicine & MEU Co-ordinator welcomed the audience and gave an overview of the Orientation programme**



**Dr. G.S. Narshetty, Dean, MGM Medical College, Kamothe addressing the PG students**



**Dr. Bharat Dhareshwar, Professor & HOD, Geriatric Medicine addressing the PG students**



**Dr. Kalpana Rajivkumar, Professor & HOD, ENT addressing the PG students**



**Dr. Rahul Kadam, Professor & HOD, Orthopaedics addressing the PG students**



**Dr. Prasad Waingankar, Professor & HOD, Community Medicine addressing the PG students**



**Dr. Rahul Peddawar, Medical Superintendent, MGM Hospital, Kamothé addressing the PG students**



**Dr. Kuldeep Salgotra, Hospital Director, MGM Hospital, Kamothé addressing the PG students**



**Dr. Sushil Kumar, Professor & HOD, OBGY addressing the PG students**



**Dr. Bageshree Seth, Professor, Paediatrics addressing the PG students**



**Dr. D.B. Bhusare, Professor & HOD, Emergency Medicine addressing the PG students**



**Dr. Pankaj Patil, Professor, Family Medicine addressing the PG students**



**Dr. Darpan Kaur, Professor, Psychiatry addressing the PG students**



**Dr. Sameer Kadam, Professor & HOD, General Surgery addressing the PG students**



**Dr. Prakash Khandelwal, Professor & HOD, Pharmacology addressing the PG students**



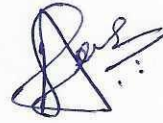
**Dr. Sandeep Rai, Professor, General Medicine addressing the PG students**



**Students expressing their expectations and responsibilities**

**Conclusion:**

The Medical Education Unit of MGM Medical College, Navi-Mumbai successfully conducted PG Orientation Programme for MD/MS students (batch 2023-2024) on 18/9/2023. The total number of PGs who attended the Induction programme were 53. The PG students enthusiastically participated in the Orientation programme and found it interesting, informative and interactive.



Dr. (Mrs.) Mrunal M. Pimparkar  
Coordinator, Medical Education Unit  
Professor, Community Medicine,  
MGM Medical College, Navi-Mumbai.

**Co-ordinator**  
**Medical Education Unit**  
**M.G.M. Medical College,**  
**Kamothe, Navi Mumbai-410209**





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### MEDICAL EDUCATION UNIT

PG Orientation Programme for MD/MS students (Admitted batch 2023-2024)  
Date: 18/9/2023, by Medical Education Unit, MGM Medical College, Navi-Mumbai. Date: 15/9/2023

#### Programme schedule

Timings	
2.30 pm – 2.40 pm	Inauguration
2.40 pm – 2.50 pm	Welcome and overview of the Orientation programme. - <b>Dr. Mrunal Pimparkar, Medical Education Unit Coordinator &amp; Professor, Community Medicine</b>
2.50 pm – 3.10 pm	Overview of the Institute, academics, research, roles and responsibilities of PGs, teaching, infrastructure. - <b>Dr. G. S. Narshetty, Dean, MGM Medical College, Kamothe</b>
3.10 pm- 3.25 pm	MGM Hospital infrastructure, facilities, and code of conduct. - <b>Dr. Kuldeep Salgotra, Hospital Director, MGM Hospital, Kamothe</b>
3.25 pm- 3.40 pm	Roles and responsibilities of PGs while working in hospital - <b>Dr. Rahul Peddawar, Medical Superintendent, MGM Hospital, Kamothe</b>
3.40 pm – 4.40 pm	<b>Briefing by HODs and Senior Professors</b> about respective Department infrastructure, working schedule and pattern, activities, code of conduct, roles and responsibilities of PGs, District Residency Programme, Research.
4.40 pm -4.55 pm	<b>Interaction with PG students</b>
4.55 pm- 5.00 pm	<b>Vote of Thanks-</b> Dr. Mrunal Pimparkar, Medical Education Unit Coordinator

Dr. (Mrs.) Mrunal M. Pimparkar  
Coordinator, Medical Education Unit  
Professor, Community Medicine,  
MGM Medical College, Navi-Mumbai.

**Co-ordinator**  
**Medical Education Unit**  
**M.G.M. Medical College,**  
**Kamothe, Navi Mumbai-410209**



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Tel no - 022/27433404, Email - [mgmmcmeu@gmail.com](mailto:mgmmcmeu@gmail.com)

Date: 18.09.2023

**Subject - PG Orientation Program for MD/MS Students  
Admitted Batch 2023-2024**

Date - 18.09.2023, Time - 02.30 pm onwards

Venue - Lecture Hall 2, Ground Floor, MGM Medical college Building, Kamothe, Navi Mumbai.

Sr. No.	Name	Course	Mobile no	Email ID	Sign
1	Dr Dexeale Kunal Mandkishov	(MS) General Surgery	7972689085	kddexeale05@gmail.com	
2	Dr Niraad Rahul Bhat	(MD) General medicine	9869228238	niraad.bhate1769@gmail.com	
3	Dr. Hrishikesh D Hulawale	MD General medicine	7620938545	hdhulawale@gmail.com	
4	Dr. Rohan Singh	M.D. General medicine	8879849994	rohansingh02@gmail.com	
5	Dr. Patel Sharwa Ramjit	M.D. Radiodiagnosis	9763029175	sharwa02r@gmail.com	
6	DR. TUSHAR SUDHIR SHARAN	MD. RADIO DIAG	9082522938	tusharsharan@gmail.com	
7	Dr. Imaad Ali Bohawatekar	MD Radiodiagnosis	7738920696	imaad99@gmail.com	
8	Dr. Harshali Mehandarkar	MS. OBGYN	9820085031	drharshali10@gmail.com	

**Co-ordinator**  
Medical Education Unit  
MGM Medical College



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Date – 18.09.2023, Time – 02.30 pm onwards

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Sr. No.	Name	Course	Mobile no	Email ID	Sign
9	Dr Himani Jivani	OBG Y	9574811444	himanijivani27@gmail.com	Himani
10	Dr. Vishakha Mitra	MSOBGY	9836035351	vishakha.mitra0201@gmail.com	Vishakha
11.	Dr. Sawali M. More	MSOBGY	9130734747	more.sawali047@gmail.com	Sawali
12.	Dr. L.SREE MOUNICA	MSOBGY	9535821600	mouni-795@gmail.com	Mounica
13.	Dr. Richika Singh	Pediatrics	7030524748	richika7@gmail.com	Richika
14.	Dr. Nikita Samal	MD. Dermatology	7378565999	nikita.samal98kw@gmail.com	Nikita
	Dr. Dudetula Mehanag	M.D. Pediatrics	8008571325	mehanag.chikku@gmail.com	Mehanag
	Dr Archana B.S	MD anaesthesia	8088864824	archana.bsarch@gmail.com	Archana

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Sr. No.	Name	Course	Mobile no	Email ID	Sign
17.	Dr. Nadupuri Sai Anusha	MD Anaesthesiology	8978659127	Nadupuri.anusha@gmail.com	Anusha
18.	K. Srinish	MS Gen. Surgery	7702966523	Kannu.k1997@gmail.com	K. Srinish
19.	Dr. Ashish Purohit	MS Traumatology	8003421887	AASHISHPUR0707@GMAIL.COM	Ashish
20	Vinit Ramesh	MS General Surgery	9920919931	vinit.vinit321@gmail.com	Vinit
21	Dr. Tejaswa Singh	MD General medicine	8770658473	tejaswasingh97@gmail.com	Tejaswa
22	Dr. Mani Vroddia	MD General Medicine	9824589248	manivroddia221@gmail.com	Mani
	Brijpal Singh	MD General Medicine	7028851064	singhjonu005@gmail.com	Brijpal
23.	Jitendra B. Gite	MS ORTHO	8468908263	jitenjdragite3996@gmail.com	Gite

**Co-ordinator**  
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Kamothe, Navi Mumbai - 410209



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Sr. No.	Name	Course	Mobile no	Email ID	Sign
25.	Dr. Abhishek Chaturvedi.	MS Orthopaedics.	9820934014	chaturvediabhishek96@ gmail.com.	
26.	Dr. Yash Suresh Patel	M.S. Orthopaedics	9099195716	yashrox78@ gmail.com	
27.	Dr. Anshuman Karak	M.S. Orthopaedics	8210196788	anshumankarak25@ gmail.com	Anshuman
28.	Dr. Sakshi Pradhan	MS orthopaedics	7718979258	sakpradhan.99@gmail.com	Sakshi
29.	Dr. Rutuja Kakad	MB Radio- diagnosis	7738620272	rutujakakad68338@ gmail.com	Rutuja
30.	Dr. Akshay Kumar Patil	MD Emergency Medicine	9740630975	patil.akshay486@quora.com	
31.	Dr. Siddharth Mishra	M.S. Orthopaedics	9323793500	sidd199925@gmail.com	sidsiddharth
32.	Dr. Reshmi Sayad Ahmed	M.D Emergency Medicine	7006947436	reshmisayad@gmail.com	

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Sr. No.	Name	Course	Mobile no	Email ID	Sign
33	Dr. Shruti V. Menon	MD Emergency Medicine	9833472276	shrutivm19@gmail.com	
34	Dr. Manali S. Deshmukh	MD Emergency Medicine	9422932125	manali3125@gmail.com	
35	Dr. Hasanah Ali	MD Anaesthesiology	9136171666	HASANAHALI6@gmail.com	
36	Dr. Aishwarya Shinde	MD Psychiatry	8100515151	aishwarya.3007@icloud.com	
37	Dr. Mrunalini Shinde	MS Ophthalmology	7387396688	mrunalsay5@gmail.com	
38	Dr. Janhvi Gharat	MD Paediatrics	7400392246	janhvigharat23@gmail.com	
39	Dr. VIRA VIJAY CHAVAN	MD Paediatrics	9619941731	virachavan9@gmail.com	
40	Dr. SAI SIKHA	MD Psychiatry	9439550744	medicsai3303@gmail.com	

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Sr. No.	Name	Course	Mobile no	Email ID	Sign
41	DR - ARUSHI PANDYA	OBGY	983366771	arushipandya1998@gmail.com	
42	DR. SANYA BHARDWAJ	PEDS	7349482309	sanyabhardwaj97@gmail.com	
43	DR. SANIKA NAGARE	OBGY	9167197585	nagaresanika@gmail.com	
44	Dr. Vaishnavi Jalake	FAMILY MEDICINE	8669499176	dr.vajalake13@gmail.com	
45	DR. R. SASHRIKA	TRAUMA SURGERY	8220687478	sashrampete@gmail.com	
46	Dr. Maithi Patel	Pathology	8619539801	patelmaithiyos@gmail.com	
47	Dr. Trivedi Hardi	Pathology	8238576684	trivedihardi0@gmail.com	
48	Dr. SANIKA SHIRKE	GENERAL SURGERY	9004445763	sanikavshirke@gmail.com	

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Date: 18.09.2023

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**Date – 18.09.2023, Time – 02.30 pm onwards**

**Venue – Lecture Hall 2, Ground Floor, MGM Medical college Building, Kamothe, Navi Mumbai.**

Sr. No.	Name	Course	Mobile no	Email ID	Sign
49.	Dr. SHRIYA MEECHERI	Anaesthesiology	9930805537	<a href="mailto:jmeecheri@gmail.com">jmeecheri@gmail.com</a>	
50	Dr. MERIN ELIAS	Geriatrics	8606745945	<a href="mailto:merineliasfem92@gmail.com">merineliasfem92@gmail.com</a>	
51	Dr. ISHA BHATT	GEN MEDICINE	7622021873	<a href="mailto:bhatt.isha14@gmail.com">bhatt.isha14@gmail.com</a>	
52	Dr. RIYA MAHESHWARI	DERMATOLOGY	8239740411	<a href="mailto:maheshwariija1997@gmail.com">maheshwariija1997@gmail.com</a>	
53.	Dr. DANYA JAWAHAR.	COMM MEDICINE	6282203781	<a href="mailto:danyajawahar234@gmail.com">danyajawahar234@gmail.com</a>	

**Co-ordinator**  
Medical Education Unit  
M.G.M. Medical College,  
Kamothe, Navi Mumbai-410209





## CLINICAL TRIAL AGREEMENT

The Clinical Trial Agreement (“**Agreement**”) is made by and between:

- **Mahatma Gandhi Mission’s Medical College & Hospital**, having a place of business at N-6, CIDCO, Aurangabad – 431003, Maharashtra, India (the “**Institution**”), and
- **Dr. Hafiz Mohd Deshmukh**, having a place of business at Mahatma Gandhi Mission’s Medical College & Hospital, N-6, CIDCO, Aurangabad – 431003, Maharashtra, India (the “**Investigator**”), and
- **Meticulous Healthcare and Research Services LLP** at House No 9-1-143, Sharif Colony, Lane No 6, Near Rashion Shop No. 132, Kat Kat Gate, Aurangabad-431001, Maharashtra, India (the “**Research Company**”) but if no such third party is required, delete the references to “Research Company” here and the references to Research Company in italics below, and
- IQVIA RDS (India) Private Limited, having a place of business at Omega Embassy Tech Square Marathahalli - Sarjapur Outer Ring Road, Kadubeesanahalli, Bangalore – 560102, Karnataka, India (“**IQVIA**”).

Each a “Party” and together the “Parties”.

<b>Protocol Number:</b>	BUS-P3-01 (CALM-1)
<b>Protocol Title:</b>	A Phase 3, 52-Week, Randomized, Double-Blind, Placebo-Controlled, Parallel-Arm Efficacy and Safety Study with Open-Label Extension of BLU-5937 in Adult Participants with Refractory Chronic Cough, Including Unexplained Chronic Cough (CALM-1)
<b>Protocol Date:</b>	04 August 2022
<b>Sponsor:</b>	Bellus Health Inc., a wholly owned subsidiary of GSK plc
<b>Country where Site is Conducting Study</b>	India
<b>Investigator:</b>	Dr. Hafiz Mohd Deshmukh: “an employee of Institution”
<b>Key Enrollment Date:</b>	<b>100 Calendar Days after Site Initiation Visit (being the date by which Site must enrol at least one (1) subject as more specifically set out in section 1.7 “Key Enrollment Date” below)</b>
<b>IRB/IEC</b>	Name of the IEC: MGM Ethics Committee for Research On Human Subject Address: MGM Medical College and Hospital, N-6, CIDCO, Aurangabad - 431003, Maharashtra, India IEC Chairperson Name: Dr. Sachin Bhagwat IEC Contact Number: +91 9422212062

The following additional definitions shall apply to this Agreement:

**Protocol:** the clinical protocol referenced above as it may be modified from time to time by the Sponsor (defined below).

Clinical Trial Agreement – IQVIA Global template – 1 May 2019  
Bellus Health Cough, Inc. \_BUS-P3-01 (CALM-1)  
Mahatma Gandhi Mission’s Medical College & Hospital\_Dr. Hafiz Mohd Deshmukh \_Final dated  
21Feb2024

Case Report Form or CRF: case report form (paper or electronic) to be used by Site to record all of the Protocol-required information to be reported to Sponsor on each Study Subject (defined below).

Study: the clinical trial that is to be performed in accordance with this Agreement and the Protocol for purposes of gathering information about the compound/medical device identified in the Protocol.

Study Subject: an individual who participates in the Study, either as a recipient of the Investigational Product (defined below) or as a control.

Study Staff: the individuals involved in conducting the Study under the direction of the Investigator.

Investigational Product: the investigational product to be used in the Study, and other products which are required by the Protocol to be used in the Study as a comparator or in combination with the investigational product.

Good Clinical Practices or GCPs: International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Harmonised Tripartite Guideline for Good Clinical Practice as amended from time to time and the principles set out in the Declaration of Helsinki as revised from time to time.

Sponsor: the sponsor of the Study.

Medical Records: the Study Subjects' primary medical records kept by the Institution on behalf of the Investigator, including, without limitation, treatment entries, x-rays, biopsy reports, ultrasound photographs and other diagnostic images.

Study Data: all records and reports, other than Medical Records, collected or created pursuant to or prepared in connection with the Study including, without limitation, reports (e.g., CRFs, data summaries, interim reports and the final report) required to be delivered to Sponsor pursuant to the Protocol and all records regarding inventories and dispositions of all Investigational Product.

Government Official: any officer or employee of a government or of any ministry, department, agency, or instrumentality of a government; any person acting in an official capacity on behalf of a government or of any ministry, department, agency, or instrumentality of a government; any officer or employee of a company or of a business owned in whole or part by a government; any officer or employee of a public international organization such as the World Bank or the United Nations; any officer or employee of a political party or any person acting in an official capacity on behalf of a political party; and/or any candidate for political office; any doctor, pharmacist, or other healthcare professional who works for or in any hospital, pharmacy or other healthcare facility owned or operated by a government agency, ministry or department.

Item(s) of Value: should be interpreted broadly and may include, but is not limited to, money or payments or equivalents, such as gift certificates; gifts or free goods; meals, entertainment, or hospitality; travel or payment of expenses; provision of services; purchase of property or services at inflated prices; assumption or forgiveness of indebtedness; intangible benefits, such as enhanced social or business standing (e.g., making donations to government official's favored charity); and/or benefits to third persons related to government officials (e.g., close family members).

Loaned Equipment: means any equipment temporarily provided to Institution by Sponsor or by a Sponsor Affiliate pursuant to this Agreement only for use in the Study, including, but not limited to, computer hardware and software if provided for the Investigator and Study Staff to use, collect, enter, and report Study data to Sponsor.

**RECITALS:**

**WHEREAS**, IQVIA is providing clinical research organisation services to Sponsor under a separate contract between IQVIA and Sponsor. IQVIA's services include monitoring of the Study and contracting with clinical research sites;

**WHEREAS**, the Institution and Investigator (hereinafter jointly the "Site") are willing to conduct the Study and IQVIA requests the Site to undertake such Study.

**NOW THEREFORE**, the following is agreed:

**1. CONDUCT OF THE STUDY**

**1.1. Compliance with Laws, Regulations, and Good Clinical Practices**

Site agrees that Site and Study Staff shall perform the Study at Institution in strict accordance with this Agreement, the Protocol, any and all applicable local, national and international laws regulations and guidelines, including in particular, but without limitation, GCPs. Site and Study Staff acknowledge that IQVIA and Sponsor, and their respective affiliates, need to adhere to the provisions of (i) the Bribery Act 2010 of the United Kingdom (Bribery Act); (ii) the Foreign Corrupt Practices Act 1977 of the United States of America (FCPA) and (iii) any other applicable anti-corruption legislation.

**1.2. Informed Consent Form**

Site agrees to use an informed consent form that has been approved by Sponsor and is in accordance with applicable regulations and the requirements of the Institutional Review Board ("IRB") or Independent Ethics Committee ("IEC") that is responsible for reviewing the Study. Site shall obtain the prior written informed consent of each Study Subject.

**1.3. Recordkeeping; Access**

**1.3.1. Collection, Storage and Destruction.** Site shall make and maintain records regarding the Study as required by the Protocol, applicable law, and Good Clinical Practices, and in accordance with Institution's standard procedures. Site will retain such records for the maximum period required by applicable law in the country in which Site are conducting the Study. After the expiration of the record retention period, Institution shall delete or destroy Institution's Study records (except Medical Records or source materials owned or solely controlled by Institution) in accordance with Institution's records deletion or destruction practices. Institution and Investigator are responsible to communicate to Sponsor any change in Institution's or Investigator's custodianship and/or location of the records during the record retention period.

**1.3.2. Ownership.** Institution shall retain ownership of Medical Records. The Institution and the Investigator hereby assign to Sponsor all of their rights, title and interest, including intellectual property rights, to all Confidential Information (as defined below) and any other Study Data.

**1.3.3. Access, Use, Monitoring and Inspection.** Site shall provide original or copies (as the case may be) of all Study Data to IQVIA and Sponsor for Sponsor's use. Site shall afford Sponsor and IQVIA and their representatives and designees reasonable access to Site's facilities and to Study records so as to permit Sponsor and IQVIA and their representatives and designees to monitor the Study.

Site shall afford regulatory authorities reasonable access to Site's facilities and to Medical Records and Study Data, and the right to copy Study records.

The Site agrees to cooperate with the representatives of IQVIA and Sponsor, and the Site agrees to ensure that the employees, agents and representatives of the Site do not harass, or otherwise create a hostile working environment for such representatives.

The Site shall immediately notify IQVIA of, and provide IQVIA copies of, any inquiries, correspondence or communications to or from any governmental or regulatory authority relating to the Study, including, but not limited to, requests for inspection of the Site's facilities, and the Site shall permit IQVIA and Sponsor to attend any such inspections. The Site will make reasonable efforts to separate, and not disclose, all Confidential Information that is not required to be disclosed during such inspections.

- 1.3.4. License.** Sponsor hereby grants to Institution a perpetual, non-exclusive, nontransferable, paid-up license, without right to sublicense, to use Study Data (i) subject to the obligations set forth in section 3 "Confidentiality", for internal, non-commercial research and for academic purposes, and (ii) for preparation of publications in accordance with Section 5 "Study Transparency and Publication Rights".
- 1.3.5. Survival.** This section 1.3 "Recordkeeping; Access" shall survive termination or expiration of this Agreement.

#### **1.4. Duties of Investigator**

Investigator is responsible for the conduct of the Study at Institution and for supervising any individual or party to whom the Investigator delegates Study-related duties and functions. In particular, but without limitation, it is the Investigator's duty to review and understand the information in the Investigator's Brochure or device labeling instructions, to ensure that all informed consent requirements are met, to ensure that all required reviews and approvals by applicable regulatory authorities and IRBs or IECs are obtained, and to review all CRFs to ensure their accuracy and completeness.

If the Investigator and Institution retain the services of any individual or party to perform Study-related duties and functions, the Institution and Investigator shall ensure this individual or party is qualified to perform those Study-related duties and functions and shall implement procedures to ensure the integrity of the Study-related duties and functions performed and any data generated.

Investigator agrees to provide a written declaration revealing Investigator's possible economic or other interests, if any, in connection with the conduct of the Study or the Investigational Product.

Investigator agrees to provide a written declaration revealing Investigator's disclosure obligations, if any, with the Institution in connection with the conduct of the Study and the Investigational Product.

Site agrees to provide prompt advance notice to Sponsor and IQVIA if Investigator will be leaving the Institution or is otherwise no longer able to perform the Study. The appointment of a new Investigator must have the prior approval of Sponsor and IQVIA.

#### **1.5. Adverse Events**

The Site shall report adverse events and serious adverse events as directed in the Protocol and by applicable laws and regulations. The Site shall cooperate with Sponsor in its efforts to follow-up on any adverse events. The Site shall comply with its IRB/IEC reporting obligations.

Sponsor will promptly report to the Site, the Site's IRB/IEC, and IQVIA, any finding that could affect the safety of participants or their willingness to continue participation in the Study, influence the conduct of the Study, or alter the Site's IRB/IEC approval to continue the Study.

#### **1.6. Use and Return of Investigational Product and Equipment**

Sponsor or a duly authorized agent of Sponsor, shall supply Institution or Investigator with sufficient amount of Investigational Product as described in the Protocol.

The Site shall use the Investigational Product solely for the purpose of properly completing the Study and shall maintain the Investigational Product as specified by Sponsor and according to applicable laws and regulations, including storage in a locked, secured area at all times.

Upon completion or termination of the Study, the Site shall return or destroy, at Sponsor's option, the Investigational Product and materials and all Confidential Information (as defined below) at Sponsor's sole expense.

Institution and Investigator shall comply with all laws and regulations governing the disposition or destruction of Investigational Product and any instructions from IQVIA that are not inconsistent with such laws and regulations.

Institution agrees that no title to nor any proprietary rights related to the Loaned Equipment is transferred to Institution, that the Loaned Equipment will be used only for the Study and only as described in the Protocol and any other written directions provided by Sponsor, that the Loaned Equipment will not be transferred by Institution to the possession of any third party without the written consent of Sponsor, and that, at Sponsor's request or the completion of the Study, Institution will return the Loaned Equipment and all related training materials and documentation to Sponsor or its designated agent.

Following reasonable advance notice, Investigator and Study Staff will attend scheduled training to use the Loaned Equipment. The Loaned Equipment will be kept in secure location and Institution will be responsible for any theft, damage, or loss to the Loaned Equipment other than normal wear and tear. Institution will arrange and pay for any required internet connection, telephone line, and/or facsimile line as necessary to use the Loaned Equipment. If Institution fails to return the Loaned Equipment within the timeframe Sponsor specified, Institution will reimburse Sponsor for any penalties, late fees, and/or replacement costs.

Institution acknowledges that the Loaned Equipment may involve valuable intellectual property of the Loaned Equipment manufacturer. Institution will not violate and will take precautions to ensure that those with access to the Loaned Equipment do not violate these proprietary rights.

#### **1.7. Key Enrollment Date**

The Site understands and agrees that if Site has not enrolled at least one (1) Study Subject by the Key Enrollment Date then IQVIA may terminate this Agreement in accordance with Section 15 "Term & Termination" Sponsor/IQVIA has the right to limit enrollment at any time.

#### **1.8 Human Biological Samples**

Institution will collect, retain and/or use any biological material of human origin, including any derivatives, progeny, or sub-cellular structures collected from Study Subjects as may be set forth in the Protocol, or that can be identified as coming from a patient treated with the Investigational Product provided under this Agreement, and tangible materials directly or indirectly derived from such samples ("HBS") solely as set forth in the Protocol, or as required for standard of care. Institution will ensure all such collection, use, storage, and shipping complies with the terms of this Agreement, the Protocol, and with all applicable laws and codes of practice and guidance relating to the collection, storage, use, shipping, and disposal of human biological materials in the conduct of the Study. Institution and Sponsor will mutually agree to appropriate informed consent (including, as appropriate, for any genetic analyses) for the Study and for research use of any human biological materials, with ethics committee approval. Institution will provide Sponsor with quantities of HBS as required by the Protocol. Sponsor may use such HBS as specified in the Protocol and as permitted in the informed

consent signed by the Study Subject (or their legal representative) and by applicable law. The informed consent will permit Sponsor its affiliates, and its designees' (including third party laboratories contracted by Sponsor for the management, testing and/or storage of the HBS collected under the Study) access to HBS, including for research and drug development purposes.

During the term of this Agreement and thereafter, Institution shall not retain or use HBS for any research purpose other than that described in the Protocol without Sponsor's prior written consent. Upon completion, early termination or expiration of the Study or this Agreement, Institution shall notify Sponsor of any left-over HBS and the Institution, as directed by Sponsor, shall either (i) return any such left-over HBS to Sponsor, or (ii) destroy them with destruction certified in writing to Sponsor. Institution agrees that any HBS collected as part of the Study that are transferred to Sponsor or a Sponsor designee, or held by Institution for Sponsor, will be under the custodianship and control of Sponsor.

In the event Institution uses HBS in breach of their obligations under this Agreement (an "Unauthorized Use"), Institution agrees that Sponsor shall be the sole and exclusive owner of any inventions conceived or reduced to practice in connection with the Unauthorized Use. Institution shall execute and deliver any documents of assignment and conveyance to effectuate the ownership of Sponsor in the invention and any intellectual property rights therein.

## **2. PAYMENT**

In consideration for the proper performance of the Study by Site in compliance with the terms and conditions of this Agreement, payments shall be made in accordance with the provisions set forth in Attachment A, with the last payment being made after the Site completes all its obligations hereunder, and IQVIA has received all properly completed CRFs and, if IQVIA requests, all other Confidential Information (as defined below).

## **3. CONFIDENTIALITY**

### **3.1 Definition**

"Confidential Information" means the confidential and proprietary information of Sponsor and includes (i) all information disclosed by or on behalf of Sponsor to Institution, Investigator or other Institution personnel, including without limitation, the Investigational Product, technical information relating to the Investigational Product, all Pre-Existing Intellectual Property (as defined in Section 4) of Sponsor, and the Protocol; and (ii) Study enrollment information, information pertaining to the status of the Study, communications to and from regulatory authorities, information relating to the regulatory status of the Investigational Product, and Study Data and New IP (as defined in Section 4).

Confidential Information shall not include information that:

- (i) can be shown by documentation to have been public knowledge prior to or after disclosure by Sponsor, other than through wrongful acts or omissions attributable to Investigator, Institution or any of its personnel;
- (ii) can be shown by documentation to have been in the possession of Investigator, Institution or any of its personnel prior to disclosure by Sponsor, from sources other than Sponsor that did not have an obligation of confidentiality to Sponsor;
- (iii) can be shown by documentation to have been independently developed by Investigator, Institution or any of its personnel; or
- (iv) is permitted to be disclosed by written authorization from Sponsor.

### **3.2 Obligations**

Site and Site's personnel, including Study Staff shall not

- (i) use Confidential Information for any purpose other than the performance of the Study or
- (ii) disclose Confidential Information to any third party, except as permitted by this Section 3 or by Section 5 "Study Transparency and Publication Rights", or as required by law or by a regulatory authority or as authorized in writing by the disclosing party.

To protect Confidential Information, Site agrees to:

- (i) collect, record, use, retain, access, transfer, store and safeguard Confidential Information in accordance with generally accepted industry standards and the terms of this Agreement. Institution shall ensure that reasonable and appropriate administrative, technical, and physical safe guards for protecting Confidential Information.
- (ii) limit dissemination of Confidential Information to only those Study Staff having a need to know for purposes of performing the Study; and
- (iii) advise all Study Staff who receive Confidential Information of the confidential nature of such information.

Nothing herein shall limit the right of Site to disclose Study Data as permitted by Section 5 "Study Transparency and Publication Rights."

### 3.3 Compelled Disclosure

In the event that Institution or Investigator receives notice from a third party seeking to compel disclosure of any Confidential Information, the notice recipient shall provide Sponsor with prompt notice so that Sponsor may seek a protective order or other appropriate remedy. In the event that such protective order or other remedy is not obtained, the notice recipient shall furnish only that portion of the Confidential Information which is legally required to be disclosed and shall request confidential treatment for the Confidential Information.

### 3.4 Return or Destruction

Upon termination of this Agreement or upon any earlier written request by Sponsor at any time, Site shall return to Sponsor, or destroy, at Sponsor's option, all Confidential Information other than Study Data.

### 3.5 Survival

This Section 3 "Confidentiality" shall survive termination or expiration of this Agreement for ten (10) years.

## 4. INTELLECTUAL PROPERTY

### 4.1 Pre-existing Intellectual Property

Ownership of inventions, discoveries, works of authorship and other developments existing as of the Effective Date and all patents, copyrights, trade secret rights and other intellectual property rights therein (collectively, "**Pre-existing Intellectual Property**"), is not affected by this Agreement, and no Party or Sponsor shall have any claims to or rights in any Pre-existing Intellectual Property of another, except as may be otherwise expressly provided in any other written agreement between them.

### 4.2 New Intellectual Property



For purposes of this Section 4, the term "**New Intellectual Property or New IP**" means any discovery, development, invention (whether patentable or not), modification, improvement, formula, process, composition of matter, formulation, use, method of use or delivery, specification, computer program or model and related documentation, know-how (including all technical information, both secret and non-secret), trade secret, or work of authorship together with all translations, adaptations, derivations, and combinations thereof, and all documentation, specifications, drawings, graphics, databases, recordings, and other copyrightable works made by Institution, Investigator(s), or Study Staff: (1) in connection with the Study; or (2) which incorporates Sponsor Confidential Information.

#### **4.3 Assignment of New IP**

Institution will notify Sponsor, promptly and in writing, of any New IP. Institution hereby assigns and will cause to be assigned by Investigators and Study Staff, to Sponsor and/or to Sponsor's Affiliates any and all rights, title, and interest in any New IP, including, without limitation, all copyright interests in any Sponsor Publication each without additional consideration from Sponsor. .

#### **4.4 Patent Prosecution**

If Sponsor requests, Institution will execute and will cause Investigators and Study Staff to execute any instruments or testify as Sponsor deems necessary for Sponsor and Sponsor's Affiliates to draft, file, and prosecute patent applications, defend patents, or to otherwise protect Sponsor's interest in New IP. Sponsor will reimburse Institution for reasonable and necessary expenses incurred.

#### **4.5 Survival**

This Section 4 "Intellectual Property" shall survive termination or expiration of this Agreement.

### **5. STUDY TRANSPARENCY AND PUBLICATION RIGHTS**

#### **5.1 Publication and Disclosure**

5.1.1. Sponsor will post (1) a Study Protocol summary on a publicly available Protocol register prior to the enrollment of Study Subjects and (2) a Study results summary on a publicly available result register no later than twelve (12) months following completion of the Study at all Study sites as defined in the Study Protocol. Posting of summary Study results may occur prior to publication of Study results in the peer-reviewed literature. Sponsor will also post full Study Protocol and statistical analysis plan at the time of results summary posting. After the Study is published in a scientific journal, Sponsor may list the Study on an external website for patient-level data sharing for further research and may also make available the full Study report on the GSK Study Register on its public-facing website.

5.1.2. First publication and all subsequent publications of the Study results from all Study sites ("Sponsor Publication(s)") or disclosure(s) of the Study results shall be coordinated by Sponsor. Any participation of Investigator or other representatives of Institution as a named author of the Sponsor Publication will be determined in accordance with the International Committee of Medical Journal Editors ("ICMJE") Uniform Requirements for Manuscripts (or if more stringent, the authorship criteria of the specific journal). The Institution and Investigator acknowledge that the enrollment of Study Subjects alone is not a qualification for authorship. If the Investigator or other representative of Institution is a named author of the Sponsor Publication, as an author the Investigator or such other Institution representative will enter into a written author agreement prior to the beginning of the work on the Sponsor Publication.

5.1.3. Sponsor may make public the names of the Investigator and the Institution as part of a list of investigators and institutions conducting the Study when making either

Protocol or results summary register postings. Institution and Investigator agree that Sponsor may make public the amount of funding provided to Institution by Sponsor for the conduct of the Study and may identify Institution and Investigator as part of this disclosure. Investigator agrees that when they speak publicly or publish any article or letter about a matter related to the Study or Study Product or that otherwise relates to Sponsor, Investigator will disclose that they were an Investigator for the Study.

- 5.1.4. Institution, consistent with scientific standards and in a scientific forum, may publish or present the Study results from Institution Study data (an "Institution Publication"), provided that the Institution Publication does not also disclose any Sponsor Confidential Information other than the Study results from Institution's Study data. Institution shall submit to Sponsor for review and comment any proposed Institution Publication at least thirty (30) days prior to submitting the Institution Publication to any third party. If Sponsor requests a delay in order to file patent applications relating to New IP, Institution agrees to delay submitting the Institution Publication to any third party for up to one hundred twenty (120) days after Sponsor's request. Institution also agrees that any Institution Publication shall only be made after the Sponsor Publication(s), and consistent with any limitations and restrictions that may apply, provided that the Sponsor Publication is submitted within eighteen (18) months after last Study Subject last visit at all sites as defined in the Study Protocol. The Institution Publication will reference the Sponsor Publication(s). Institution agrees that Sponsor's financial support of the Study will be disclosed in any Institution Publication. Institution shall ensure that Investigator complies with the obligations identified in this subclause.

## **5.2 Media Contacts**

Institution and Investigator shall not and shall ensure that its personnel do not engage in interviews or other contacts with the media, including but not limited to newspapers, radio, television and the Internet, related to the Study, the Investigational Product, New Intellectual Property, or Study Data without the prior written consent of Sponsor. This provision does not prohibit publication or presentation of Study Data in accordance with this Section.

## **5.3 Use of Name, Registry and Reporting**

No Party hereto shall use any other Party's name, or Sponsor's name, in connection with any advertising, publication or promotion without prior written permission, except that the Sponsor and IQVIA may use the Site's name in Study publications and communications, including clinical trial websites and Study newsletters. Sponsor will register the Study with a public clinical trials registry in accordance with applicable laws and regulations and will report the results of the Study publicly when and to the extent required by applicable laws and regulations.

## **5.4 Survival**

This Section 5 "Study Transparency and Publication Rights" shall survive termination or expiration of this Agreement.

## **6. PERSONAL DATA**

The Site and IQVIA agree to comply with any applicable data privacy or data protection legislation in the processing of personal data, as it is defined under such applicable data privacy or data protection legislation.

## **7. INDEMNIFICATION; STUDY SUBJECT INJURY**

### **7.1 Sponsor Indemnification**

Sponsor agrees to indemnify, defend, and hold harmless Institution and its Affiliates, Investigators, Study Staff, and other Institution employees, agents, and approved Subcontractors ("Institution Indemnitees") from and against any loss, expense, cost (including settlements or ex-gratia payments made with the consent of the Parties and reasonable legal and expert fees), liability, damage, or claim by third parties for personal injury, including death, that arises out of Institution's administration of the Study Product(s) or procedures provided for by the Protocol or that arises out of the negligence or wilful misconduct of Sponsor ("Institution Claim"), provided that Sponsor shall not indemnify any Institution Indemnitee for any Institution Claim to the extent Institution Claim arose out of:

- (i) failure by Institution Indemnitees to conduct the Study in accordance with the Protocol or this Agreement; or
- (ii) the negligence or wilful misconduct or breach of statutory duty of Institution Indemnitees.

Sponsor's obligations under this clause with respect to Institution Claim are conditioned on:

- (i) prompt written notification to Sponsor of Institution Claim so that Sponsor's ability to defend or settle Institution Claim is not prejudiced; and
- (ii) Institution Indemnitees' agreement that Sponsor has full control over the defence or settlement of Institution Claim and to fully cooperate with Sponsor in the defence or settlement of Institution Claim; provided, that, Sponsor will not settle any such Institution Claim under terms that include an admission of fault or wrongdoing by any Indemnitee or which requires an Indemnitee to undertake a future course of action without that Indemnitee's written consent to such components.

## **7.2 Subject Injury**

The Site shall promptly notify IQVIA and Sponsor in writing of any claim of illness or injury actually or allegedly due to an adverse reaction to the Investigational Product and cooperate with Sponsor in the handling of the adverse event.

Sponsor shall reimburse Institution for the direct, reasonable and necessary medical expenses incurred by Institution for the treatment of any adverse event experienced by, illness of or bodily injury to a Study Subject that is caused by treatment of the Study Subject in accordance with the Protocol, except to the extent that such adverse event, illness or personal injury is caused by:

- (a) failure by Institution, Investigator or Research Company or any of their respective personnel to comply with this Agreement, the Protocol, any written instructions of Sponsor concerning the Study, or any applicable law, regulation or guidance, including GCPs, issued by any regulatory authority, or
- (b) negligence or wilful misconduct by Institution, Investigator or Research Company or any of their respective personnel, or
- (c) failure of the Study Subject to follow the reasonable instructions of the Investigator relating to the requirements of the Study.

This Section 7 "Indemnification; Study Subject Injury" shall survive termination or expiration of this Agreement.

## **8. IQVIA DISCLAIMER**

IQVIA expressly disclaims any liability in connection with the Investigational Product, including any liability for any claim arising out of a condition caused by or allegedly caused by any Study

procedures associated with such product except to the extent that such liability is caused by the negligence, willful misconduct or breach of this Agreement by IQVIA.

This Section 8 "IQVIA Disclaimer" shall survive termination or expiration of this Agreement.

#### **9. CONSEQUENTIAL DAMAGES**

Neither IQVIA nor Sponsor shall be responsible to the Site for any lost profits, lost opportunities, or other consequential damages, nor shall Site be responsible to IQVIA or Sponsor for any lost profits, lost opportunities, or other consequential damages.

Nothing herein is intended to exclude or limit any liability of any party for death or personal injury caused by the negligence of such party.

This Section 9 "Consequential Damages" shall survive termination or expiration of this Agreement.

#### **10. DEBARMENT**

The Site represents and warrants that neither Institution nor Investigator, nor any of Institution's or Investigator's employees, agents or other persons performing the Study at Institution, have been debarred, disqualified or banned from conducting clinical trials or are under investigation by any regulatory authority for debarment or any similar regulatory action in any country, and the Site shall notify IQVIA immediately if any such investigation, disqualification, debarment, or ban occurs.

This Section 10 "Debarment" shall survive termination or expiration of this Agreement.

#### **11. FINANCIAL DISCLOSURE AND CONFLICT OF INTEREST**

Upon Sponsor's or IQVIA's request, Site agrees that, for each listed or identified investigator or sub-investigator who is directly involved in the treatment or evaluation of Study Subjects, it shall promptly return to IQVIA a financial and conflict of interest disclosure form that has been completed and signed by such investigator or sub-investigator, which shall disclose any applicable interests held by those investigators or sub-investigators or their spouses or dependent children.

IQVIA may withhold payments if it does not receive a completed form from each such investigator and sub-investigator.

Site shall ensure that all such forms are promptly updated as needed to maintain their accuracy and completeness during the Study and for one (1) year after Study completion. Site agrees that the completed forms may be subject to review by governmental or regulatory agencies, Sponsor, IQVIA, and their agents, and the Site consents to such review.

The Site further consents to the transfer of its financial disclosure data to the Sponsor's country of origin and to the U.S., even though data protection may not exist or be as developed in those countries as in the Site's own country.

This Section 11 "Financial Disclosure and Conflict of Interest" shall survive termination or expiration of this Agreement.

#### **12. ANTI-KICKBACK AND ANTI-FRAUD**

Institution and Investigator agree that their judgment with respect to the advice and care of each Study Subject will not be affected by the compensation they receive from this Agreement, that such compensation does not exceed the fair market value of the services they are providing, and that

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Mahatma Gandhi Mission's Medical College & Hospital\_Dr. Hafiz Mohd Deshmukh\_Final dated 21Feb2024

no payments are being provided to them for the purpose of inducing them to purchase or prescribe any drugs, devices or products.

If the Sponsor or IQVIA provides any free products or items for use in the Study, Institution and Investigator agree that they will not bill any Study Subject, insurer or governmental agency, or any other third party, for such free products or items.

Institution and Investigator agree that they will not bill any Study Subject, insurer, or governmental agency for any visits, services or expenses incurred during the Study for which they have received compensation from IQVIA or Sponsor, or which are not part of the ordinary care they would normally provide for the Study Subject, and that neither Institution nor Investigator will pay another physician to refer subjects to the Study.

### **13. ANTI-BRIBERY**

Institution and Investigator agree that the fees to be paid pursuant to this Agreement represent fair compensation for the services to be provided by Site. Institution and Investigator represent and warrant that payments or Items of Value received pursuant to this Agreement or in relation to the Study will not influence any decision that Institution, Investigator or any of their respective owners, directors, employees, agents, consultants, or any payee under this Agreement may make, as a Government Official or otherwise, in order to assist Sponsor or IQVIA to secure an improper advantage or obtain or retain business.

Institution and Investigator further represent and warrant that neither they nor any of their respective owners, directors, employees, agents, or consultants, nor any payee under this Agreement, will, in order to assist Sponsor or IQVIA to secure an improper advantage or obtain or retain business, directly or indirectly pay, offer or promise to pay, or give any Items of Value to any person or entity for purposes of (i) influencing any act or decision; (ii) inducing such person or entity to do or omit to do any act in violation of their lawful duty; (iii) securing any improper advantage; or (iv) inducing such person or entity to use influence with the government or instrumentality thereof to affect or influence any act or decision of the government or instrumentality.

In addition to other rights or remedies under this Agreement or at law, IQVIA may terminate this Agreement if Site breaches any of the representations or warranties contained in this Section or if IQVIA or Sponsor learns that improper payments are being or have been made to or by Institution or Investigator or any individual or entity acting on its or their behalf.

### **14. INDEPENDENT CONTRACTORS**

The Investigator and Institution and Research Company and Study Staff are acting as independent contractors of IQVIA and Sponsor and shall not be considered the employees or agents of IQVIA or Sponsor.

Neither IQVIA nor Sponsor shall be responsible for any employee benefits, pensions, workers' compensation, withholding, or employment-related taxes as to the Investigator or Institution or Research Company or their staff.

It is hereby agreed and acknowledged by the Parties and Sponsor that IQVIA has no relationship whatsoever with the Research Company and that the Research Company is acting as an independent contractor of the Institution.

### **15. TERM & TERMINATION**

#### **15.1 Term**

This Agreement will become effective on the date on which it is last signed by the parties (the “Effective Date”) and shall continue until completion or until terminated in accordance with this Section 15 “Term & Termination”.

**15.2 Termination**

IQVIA may terminate this Agreement for any reason effective immediately upon written notice. The Site may terminate upon written notice if circumstances beyond the Site’s reasonable control prevent completion of the Study, or if it reasonably determines that it is unsafe to continue the Study. Upon receipt of notice of termination, the Site shall immediately cease any subject recruitment, follow the specified termination procedures, ensure that any required subject follow-up procedures are completed, and make all reasonable efforts to minimize further costs, and IQVIA shall make a final payment for visits or milestones properly performed pursuant to this Agreement in the amounts specified in Attachment A; provided, however, that ten percent (10%) of this final payment will be withheld until final acceptance by Sponsor of all CRF pages and all data clarifications issued and satisfaction of all other applicable conditions set forth herein. If a material breach of this Agreement appears to have occurred and termination may be required, then, except to the extent that Study Subject safety may be jeopardized, IQVIA may suspend performance of all or part of this Agreement, including, but not limited to, subject enrollment.

**16. NOTICE**

Any notices required or permitted to be given hereunder shall be given in writing and shall be delivered

- (a) in person,
- (b) by certified mail, postage prepaid, return receipt requested,
- (c) by e-mail of .pdf/scan or other non-editable format notice with confirmed transmission report, or
- (d) by a commercial overnight courier that guarantees next day delivery and provides a receipt, and such notices shall be addressed as follows:

To Sponsor:	<p>Name: Bellus Health Inc., a GSK company          Address: 1250 South Collegeville Rd,          Collegeville, PA 19426          United States</p> <p>Attention:          David Lipson, VP Disease Area Lead,          Respiratory          Tel: (610) 812-8446          Email: david.a.lipson@gsk.com</p> <p>With a copy to:          GSK          R&amp;D Legal Operations          Attention: General Counsel          980 Great West Road          Brentford, Middlesex, TW8 9GS, U.K.</p>
To IQVIA	<p>Name: IQVIA RDS (India) Private Limited          Address: Omega Embassy Tech Square          Marathahalli- Sarjapur Outer Ring Road,          Kadubeesanahalli, Bangalore – 560103,          Karnataka, India</p>

	<p>And to</p> <p>IQVIA Inc. Global Legal Department 100 IMS Drive Parsippany, NJ 07054 USA Attention: General Counsel Email: officeofgeneralcounsel@iqvia.com</p>
To Institution	<p>Name: Dr. Deepak Bhosle Address: Mahatma Gandhi Mission's Medical College &amp; Hospital, N-6, CIDCO, Aurangabad – 431003, Maharashtra, India</p> <p>Tel: +91-7770087870</p>
To Investigator	<p>Name: Dr. Hafiz Mohd Deshmukh Address: Mahatma Gandhi Mission's Medical College &amp; Hospital, N-6, CIDCO, Aurangabad – 431003, Maharashtra, India</p> <p>Tel: +91-8390628800</p>
To Research Company	<p>Name: Mr. Shaik Yahiya Ali</p> <p>Address: Meticulous Healthcare and Research Services LLP, House No 9-1-143, Sharif Colony, Lane No 6, Near Rashion Shop No. 132, Kat Kat Gate, Aurangabad- 431001, Maharashtra, India</p> <p>Tel: +91-9766885171</p>

## **17. FORCE MAJEURE**

The performance by either Party of any obligation on its part to be performed hereunder shall be excused by floods, fires or any other Act of God, accidents, wars, riots, embargoes, delay of carriers, inability to obtain materials, failure of power or natural sources of supply, acts, injunctions, or restraints of government or other force majeure preventing such performance, whether similar or dissimilar to the foregoing, beyond the reasonable control of the Party bound by such obligation, provided, however, that the Party affected shall exert its reasonable efforts to eliminate or cure or overcome any of such causes and to resume performance of its obligations with all possible speed.

## **18. MISCELLANEOUS**

### **18.1 Entire Agreement**

This Agreement, including its attachment(s), constitutes the sole and complete agreement between the Parties and replaces all other written and oral agreements relating to the Study.

### **18.2 No Waiver/Enforceability**

Failure to enforce any term of this Agreement shall not constitute a waiver of such term.

If any part of this Agreement is found to be unenforceable, the rest of this Agreement will remain in effect.

Clinical Trial Agreement – IQVIA Global template – 1 May 2019

Bellus Health Cough, Inc.\_BUS-P3-01 (CALM-1)

Mahatma Gandhi Mission's Medical College & Hospital\_Dr. Hafiz Mohd Deshmukh\_Final dated 21Feb2024

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### **18.3 Assignment of the Agreement**

This Agreement shall be binding upon the Parties and their successors and assigns.

The Site shall not assign or transfer any rights or obligations under this Agreement without the written consent of IQVIA and Sponsor.

Upon Sponsor's request, IQVIA may assign this Agreement to Sponsor or to a third party, and IQVIA shall not be responsible for any obligations or liabilities under this Agreement that arise after the date of the assignment, and the Site hereby consents to such an assignment. Site will be given prompt notice of such assignment by the assignee.

### **18.4 Subcontracting**

Institution may subcontract the performance of certain of its activities under this Agreement to a Subcontractor(s) approved by Sponsor in writing; provided, that (a) such approved Subcontractor(s) perform such activities in a manner consistent with the terms and conditions in this Agreement; (b) Institution causes such approved Subcontractors to be bound by and comply with the terms of this Agreement, as applicable; and, (c) Institution remains liable for such approved Subcontractor(s)'s performance. As used herein, "Subcontractor(s)" means any third party (including agents) to whom Institution has delegated any function(s) constituting a part of the Study, including a third party to whom a Subcontractor further delegates any part of the Study.

### **18.5 Third Party Beneficiary**

The Parties agree that Sponsor shall have the right to enforce any of the provisions of this Agreement as a third-party beneficiary.

Each Party to this Agreement acknowledges that except for the Sponsor, there are no third party beneficiaries with any rights to enforce any of the provisions of this Agreement.

### **18.6 Binding Authority**

IQVIA represents that Sponsor has granted IQVIA written authority to bind Sponsor to the Sponsor obligations expressly included in this Agreement and for no other purposes whatsoever.

### **18.7 Applicable Law**

This Agreement shall be interpreted under the laws of the state or province and country in which Site conducts the Study.

### **18.8. Human Rights and Ethical Standards**

Institution represents, to the best of its knowledge, that in connection with this Agreement, it does not employ child labour, forced labour, unsafe working conditions, discrimination of protected characteristic, cruel or abusive disciplinary practices in the workplace; and that it pays each employee at least the minimum wage, provides each employee with all legally mandated benefits, and complies with the all applicable laws, including laws related to working hours and employment rights in the country(ies) in which it operates.

### **18.9 Survival:**

The terms of this Agreement that contain obligations or rights that extend beyond the completion of the Study shall survive termination or completion of this Agreement, even if not expressly stated herein.

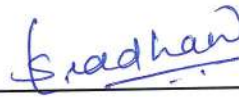
**THIS SECTION IS INTENTIONALLY LEFT BLANK; SIGNATURES FOLLOW ON NEXT PAGE**



ACKNOWLEDGED AND AGREED BY IQVIA RDS (INDIA) PRIVATE LIMITED:

By: Shweta Pradhan

Title: Director & Head, Site Management

Signature: 

Date: 23/2/2024

ACKNOWLEDGED AND AGREED BY THE INVESTIGATOR:

Name: Dr. Hafiz Mohd Deshmukh

Signature: 

Date: 27/Feb/2024

ACKNOWLEDGED AND AGREED BY MAHATMA GANDHI MISSION'S MEDICAL COLLEGE & HOSPITAL:

By: Dr. Deepak Bhosale

Title: Professor and Head Of Department Of Pharmacology And Clinical Trial Center

Signature: 


Date: \_\_\_\_\_

METICULOUS HEALTHCARE AND RESEARCH SERVICES LLP agrees to abide by all obligations placed on Institution in the provisions of this Agreement concerning Confidentiality (Section 3); Intellectual Property (Section 4); Study Transparency and Publication Rights (Section 5); Personal Data (Section 6); Debarment (Section 10); Anti-Kickback and Anti-Fraud (Section 12); and Anti-Bribery (Section 13)

ACKNOWLEDGED AND AGREED BY METICULOUS HEALTHCARE AND RESEARCH SERVICES LLP,

By: Mr. Shaikh Yahiya Ali

Title: Director

Signature: 

Date: 27/Feb/2024

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Mahatma Gandhi Mission's Medical College & Hospital\_Dr. Hafiz Mohd Deshmukh\_Final dated  
21Feb2024

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**ATTACHMENT A**  
**BUDGET & PAYMENT SCHEDULE**

**A. PAYEE DETAILS**

The Parties agree that the payee designated below is the proper payee for this Agreement, and that payments under this Agreement will be made only to the following payee (“Payee”):

Institution and Investigator acknowledge and confirm that the Payee named hereunder, is authorized to receive payment under this Agreement, and; certify, represent and agree that such payment arrangement is in accordance with the modalities, rules or policies laid down by the Institution for receipt of funding for the Study and is not in violation of any applicable national, state or local laws or regulations.

**Payee**

Payee Name	Meticulous Healthcare and Research Services LLP
Payee Address	House No 9-1-143, Sharif Colony, Lane No 6, Near Rashion Shop No. 132, Kat Kat Gate, Aurangabad-431001, Maharashtra, India
GST Number	Not Applicable
Tax ID (Tax ID must exactly match the Payee name indicated above, or tax exempt when applicable)	ABSFM8626R

**Banking Information:**

Bank Name	ICICI Bank
Bank Street	Aurangabad Branch, Raghuvir Complex, Opp. District Court
Bank City	Aurangabad
Bank State/Province	Maharashtra
Bank Postal Code	431001
Bank Country	India
Receiving Account Currency	INR
Bank Account #	004405016674
IFSC code	ICIC0000044
Swift Code (8 or 11 Characters)	Not Applicable
If the contracted payment currency does not match your bank account, you may need to provide an intermediary bank. Please contact your financial institution for details. If an intermediary bank is required, please provide Bank Name, Account Number if applicable and SWIFT Code of intermediary bank along with all other required wire instructions	

**Contact Information**

Name of Institution's Point of Contact	Dr. Hafiz Mohd Deshmukh
--	-------------------------

Phone number & Email	+91-8390628800 &dr.hafizdeshmukh@gmail.com
Language Preference	English
Name of Institution's Point of Contact payment recipient to receive payment notification and details	Shaikh Yahiya Ali
Phone number & Email	+91-9766885171 &meticulous.smo@gmail.com
Language Preference	English

In case of changes in the Payee's address or bank account number, Site is obliged to inform IQVIA Clinical Trials Payments in writing by sending an email through which Site shall provide supporting documents evidencing the changes to apac@ctp.solutions.iqvia.com.

The Parties agree that in case of changes in address which do not involve a change of Payee, tax numbers, or tax-exempt status, no further amendments are required. The Parties acknowledge that the designated Payee is authorized to receive all of the payments for the services performed under this Agreement.

If the Investigator is not the Payee, then the Payee's obligation to reimburse the Investigator, if any, is determined by a separate agreement between Investigator and Payee, which may involve different payment amounts and different payment intervals than the payments made by IQVIA to the Payee.

Investigator acknowledges that if Investigator is not the Payee, IQVIA will not pay Investigator even if the Payee fails to reimburse Investigator.

**B. MINIMUM ENROLLMENT GOAL**

Site acknowledges that Site's minimum enrollment goal is four (4) Study Subjects and that Site will use its best efforts to reach the enrolment goal within a reasonable timeframe after commencement of the Study at Site. If Site fails to adhere to this principle, IQVIA may reconsider Site's suitability to continue participation in the Study.

**C. PAYMENT TERM**

IQVIA will make payments to the Payee every 3 months, on a completed visit, as verified by data entry completion in eCRF and submission to IQVIA, per Study Subject basis in accordance with the attached budget. Ninety percent (90%) of each payment due, including any Screening Failure that may be payable under the terms of this Agreement, will be made based upon prior 3 months' enrollment data received from the Site supporting Study Subject visitation.

The balance of monies earned, up to ten percent (10%), will be pro-rated upon verification of actual Study Subject visits, and will be paid by IQVIA to the Payee upon final acceptance by Sponsor of all data entry, all data clarifications issued, the receipt and approval of any outstanding regulatory documents as required by IQVIA and/or Sponsor, the return of all unused supplies to IQVIA, and upon satisfaction of all other applicable conditions set forth in the Agreement.

Any expense or cost incurred by Site in performing this Agreement that is not specifically designated as reimbursable by IQVIA or Sponsor under the Agreement (including this Budget and Payment Schedule) is the sole responsibility of the Site.

Site represents that the services it provides under this Agreement are taxable services under the tax laws in India, and that it is required to charge applicable taxes for the services rendered to IQVIA at the prevailing rate. Site represents that it is entitled to require such payment of the

applicable taxes under the laws of India. Site undertakes to provide IQVIA with an invoice, to be sent to IQVIA at the address mentioned in Section O of this Attachment A, in respect of such taxable services and such invoice shall be in accordance with the terms of the applicable tax laws in India as may be amended from time to time or any successor legislation.

It should be noted that all payments made to the Payee are subject to Tax Deducted at Source (TDS) in accordance with India tax laws, as amended from time to time. IQVIA will deduct the tax at the time of making payments unless a valid Certificate of no deduction or NIL deduction is obtained from tax authority is made available to IQVIA.

All fees set forth in the Agreement are exclusive of any taxes and duties (other than employment-related taxes, corporate income taxes) (“Taxes”). Institution shall pay any and all Taxes that are imposed by legislation in connection with the provision of services.

All amounts specified in this Agreement are in Indian Rupees (INR) and are exclusive of GST. IQVIA will pay to the Payee any amount of GST that the Payee is required to pay in addition to the amounts set out in this Attachment A and in accordance with GST legislation.

**Major, disqualifying Protocol violations are not payable under this Agreement**

**D. BUDGET TABLE**

**MAIN STUDY**

<u>VISIT</u>	<u>VISIT AMOUNT INCLUDING 30% IOH (INR)</u>	<u>SCREEN AMOUNT IOH (INR)</u>	<u>FAILURE INCLUDING</u>
VISIT 1 – SCREENING VISIT/SCR	37226	37226	
VISIT 2 - V2	17936	0	
VISIT 3 - V3	10256	0	
VISIT 4 - V4	15213	0	
VISIT 5 - V5	18686	0	
VISIT 6 - V6	17291	0	
VISIT 7 - V7	24337	0	
VISIT 8 - V8	11968	0	
VISIT 9 - V9	11968	0	
VISIT 10 - V10	15895	0	
PHONE CALL 1 / VISIT 11 – PC1 / VC11	5546	0	
VISIT 12 - V12	15895	0	
PHONE CALL 2 / VISIT 13 – PC2 / VC13	5546	0	
VISIT 14 - V14	11968	0	
PHONE CALL 3 / VISIT 15 – PC3 / VC15	5546	0	
VISIT 16 - V16	11968	0	
VISIT 17 - V17	3602	0	
VISIT 18/EARLY TERMINATION – V18/ET	22742	0	
PHONE CALL 4 / VISIT 19 – PC4 / VC19	4087	0	
VISIT 20 - V20	10508	0	
PHONE CALL 5 / VISIT 21 – PC5 / V21	4087	0	
VISIT 22 - V22	10508	0	
PHONE CALL 6 / VISIT 23 – PC6 / V23	4087	0	
VISIT 24/V24	11843	0	

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VISIT 25 / FOLLOW-UP (END OF STUDY) - V25 / FU (EOS)	10206	0
<b>TOTAL COST PER PATIENT(DOES NOT INCLUDE OCULAR SUBSTUDY)</b>	<b>318915</b>	<b>37226</b>
TELEVISIT *	5820	5820
UNSCHEDULED VISIT **	6205	6205
RE-SCREENING *	9482	9482

\* TELEVISIT AND RE-SCREENING NOT INCLUDED IN TOTAL BUDGET

\*\*UNSCHEDULED VISIT CAN OCCUR MORE THAN ONCE, NOT INCLUDED IN TOTAL BUDGET

OR BELOW TABLE FOR REFERENCE



















**E. STUDY START-UP FEE [DO NOT INCLUDE IN INVOICE SECTION]**

A one-time, non-refundable payment will be paid in the amount of **One Lakh Indian Rupees (INR1,00,000)** to cover Study start-up activities upon completion and receipt by IQVIA of all contractual and regulatory documentation and receipt of invoice and upon completion of Site Activation.

**F. SCREENING FAILURE**

Reimbursement for screen failures will be at the amount indicated on the Screening visit of the attached budget table, not to exceed four (4) screen failures paid per one (1) Study Subject randomized. The ratio may change on direct Institution's request and with written approval of Sponsor and/or IQVIA.

To be eligible for reimbursement of a screening visit, supporting data entry must be completed and confirmed in eCRF and submitted to IQVIA along with any additional information, which may be requested by IQVIA to appropriately document the Study Subject screening procedures.

**G. RE-SCREENING VISIT PAYMENT**

Reimbursement for re-screens will be in the amount of **Nine Thousand Four Hundred and Eighty Two Indian Rupees (INR 9482)**, which includes overhead up to a maximum number of one (1) re-screen per Study Subject. To be eligible for reimbursement of the re-screening visit, supporting data entry must be completed and submitted to IQVIA and any additional information, which may be requested by IQVIA to appropriately document the Study Subject screening procedures.

**H. RUN-INFAILURE, DISCONTINUED OR EARLY TERMINATION STUDY SUBJECTS**

Reimbursement for run-in failure, discontinued or early termination Study Subjects will be prorated based on the number of confirmed completed visits, supporting data entry and confirmed in eCRF.

**I. UNSCHEDULED VISITS**

Payment for unscheduled visits will be reimbursed in the amount of **Six Thousand Two Hundred and Five Indian Rupees (INR 6205)** which includes overhead, as denoted in the Budget Table above. To be eligible for reimbursement for unscheduled visits, supporting data entry must be completed and confirmed in eCRF and submitted to IQVIA, along with any additional information which may be requested by IQVIA, to appropriately document the unscheduled visit.

**J. CONDITIONAL PROCEDURES (WITH INVOICE)**

The following conditional procedure costs will be reimbursed on a pass-through basis upon receipt of invoice in the amount indicated in the table below (which includes overhead) and as verified by IQVIA conditional procedures occurred, and the site has completed relevant data entry. Study Subject number and procedure dates must be included on the invoice for payment to be issued.

<u>Procedure</u>	<u>Procedure amount (INR)</u>
Complete physical examination, includes: a comprehensive <b>physical examination</b> including <b>one set of vital signs, height, weight, BMI</b> - for Re-Screening visit if needed	6444
Brief physical examination: Includes a problem focused <b>physical examination</b> including <b>one set of vital signs</b> for additional assessments if needed	1956
Vital signs incl. weight if applicable for additional measurements if needed	1173
Spirometry, including graphic record, total and timed vital capacity, expiratory flow rate measurement(s), forced expiratory volume (FEV), with or without maximal voluntary ventilation (MVV), pulmonary function test (PFT), lung function test for screening and/or Re-screening if needed	2000
Interpretation and Report; Spirometry, including graphic record, total and timed vital capacity, expiratory flow rate measurement(s), forced expiratory volume (FEV), with or without maximal voluntary ventilation,	567

pulmonary function test (PFT), lung function test for screening and/or Re-screening if needed	
Fractional Exhaled Nitric Oxide (FeNO) for screening and/or Re-screening if needed	1421
Single 12-lead ECG: Includes tracing, interpretation and report for additional measurements if needed and/or for Re-screening	932
Blood draw, phlebotomy, routine venipuncture for collection of specimen(s) for <b>central (hematology, clinical chemistry, male reproductive hormones if applicable, serum pregnancy if applicable, viral serology, tuberculosis if needed, biomarkers, UGT1A1 Gene Polymorphism if needed, FSH if applicable)laboratory</b> , as applicable,; simple: Includes preparation of specimen for additional/repeated/unscheduled testingand/or for Follow-up visit and/or for Re-screening	350
Urine collection for <b>local (urinalysis, urine pregnancy if applicable) and/or central (urine microscopy/macrosocopy if needed, urine drug screen) laboratory</b> , as needed for additional/repeated/unscheduled testing and/or sampling for urine pregnancytesting and/or for Re-screening	365
Urinalysis, by dip stick or tablet reagent (local lab)	800
Urine pregnancy, gonadotropin chorionic (hCG) (BetahCG); qualitative (local lab) for women of childbearing potential	920
Lab handling and/or shipping of specimen(s) to central laboratory, simple for additional/repeated/unscheduled testing and/or in case of overdoseand/or for Follow-up visit and/or for Re-screening	473
Collection, preparation, shipping and handling of samples from throat, nose, nares, sputum by swab or brushing for <b>SARS-CoV-2 PCR test</b> for additional testing if needed and/or for Re-screening	716
PK sampling in case of overdose	1074
Radiologic examination, chest; single view for screening and/or for repeated imaging	1758
Interpretation and Report: Radiologic examination, chest; single view for screening and/or for repeated imaging; for imaging performed at site only	498
Computerized axial tomography, thorax, thoracic, chest (Cat Scan) (CT Scan); without contrast material; can be used for peripheral artery tomography for screening and/or for repeated imaging	20077
Interpretation and Report; Computerized axial tomography, thorax, thoracic, chest (Cat Scan) (CTScan); without contrast material for screening and/or for repeated imaging; for imaging performed at site only	3687
Computerized axial tomography, thorax, thoracic, chest (Cat Scan) (CT Scan); with contrast material(s) for screening and/or for repeated imaging	24484
Interpretation and Report; Computerized axial tomography, thorax, thoracic, chest (Cat Scan) (CTScan); with contrast material(s) for screening and/or for repeated imaging; for imaging performed at site only	5369
Nurse - Per Hour - Attach Cough Monitor for re-screening if needed	1899
Cough Monitor Instruction - Per Visit for re-screening if needed	757
Cough Monitor Collection and Monitoring/Review - Per Visit for re-screening if needed	1123
ePRO tablet Instruction - Per Visit for re-screening if needed	757

ePRO tablet Collection and Monitoring/Review - Per Visit for re-screening if needed	1123
Concomitant medications for televisit if needed	638
Adverse events assessment for televisit if needed	646
Patient Travel - Per Visit for returning cough monitor next day (Institutional Overhead Not Applicable)	1000
Re-consent, Informed consent performed again with the same patient	1615
Serious adverse events (SAE)	2598

**K. INSTITUTION COSTS  
PHARMACY SET-UP FEE**

A one-time, non-refundable payment will be paid in the amount of **Twenty-Four Thousand Eight Hundred and Eleven Indian Rupees (INR 24,811)** to cover Pharmacy start-up/set-up activities upon completion and receipt by IQVIA of all contractual and regulatory documentation, upon Site activation and receipt of invoice.

**RECORD STORAGE/ARCHIVING FEE**

A one-time record storage payment of **Two Lakh Indian Rupees (INR 2,00,000)**, will be made upon receipt of invoice upon final acceptance by Sponsor of all data entry, all data clarifications issued, the receipt and approval of any outstanding regulatory documents as required by IQVIA and/or Sponsor, the return of all unused supplies to IQVIA, and upon satisfaction of all other applicable conditions set forth in the Agreement, and is not included in the Budget Table above. In accordance with Sponsor's Protocol requirements, Institution shall maintain all Institution Study records in a safe and secure location to allow easy and timely retrieval, when needed.

**STUDY CLOSE-OUT FEE**

A one-time, non-refundable Study Close-Out payment of **Thirty-Eight Thousand Four Hundred and Forty Seven Indian Rupees (INR 38,447)** will be made upon completion and approval by IQVIA of any outstanding data documentation (data entry completion and data clarifications issued) and regulatory documentation and upon receipt of invoice at the end of the Study.

**L. EC/IRB/IEC FEES (WHEN PAID TO SITE - FOR CENTRAL IRB CAN REMOVE COMPLETELY - REFER TO FALLBACK)**

EC/IRB/IEC costs will be reimbursed on a pass-through basis upon receipt of an invoice and are not included in the attached Budget. Any subsequent re-submissions or renewals, upon approval by IQVIA and Sponsor, will be reimbursed upon receipt of appropriate documentation.

**M. EQUIPMENT**

All materials and equipment provided ("**Equipment**") including to Sponsor or IQVIA owned or licensed proprietary resources ("**Resources**") provided by the Sponsor or IQVIA/vendors contracted by the Sponsor are and shall remain the sole property of the Sponsor/IQVIA/vendors, as the case may be.

Therefore, it is hereby agreed that such Equipment and Resources shall:

- a) be subject to removal at any time upon the Sponsor's or, IQVIA' demand provided that such removal does not prevent the Site from conducting the Study and carrying out their obligations under this Agreement;
- b) be used only for the purposes of the Study;
- c) be used in accordance with any manuals or instructions while in possession of the Site;
- d) shall remain in the same condition, ordinary wear and tear excepted. As long as the Equipment are in the possession of the Site, it is liable for maintenance or any risk of loss in connection with the Equipment during the conduct of the Study;
- e) be clearly identified as the sole property of the Sponsor/IQVIA/vendor, as applicable, by clearly stating "BELONGS TO "Name of legal owner" in order to notify any third parties, including creditors, that the legal owner retains title thereto; and
- f) upon completion or termination of the Study or at an earlier time specified by Sponsor or IQVIA, IQVIA or Sponsor, together with Site assistance, shall arrange the return of all equipment provided for the Study as soon as reasonably practicable upon request to return to the Sponsor or IQVIA or a location designated by Sponsor or



IQVIA, or if requested by the Sponsor or IQVIA in writing, arrange for the disposal of the Equipment, at the expense of the Sponsor or IQVIA, unless Sponsor and Site have a written agreement for Site to acquire the equipment.

**N. PAYMENT DISPUTES**

Site will have thirty (30) days from the receipt of final payment to dispute any payment discrepancies during the course of the Study.

**O. INVOICES**

Payments will be issued by IQVIA based on the agreed budget, Visit Budget, payment frequency and payment terms as described above. Payments will be made only upon receipt of corresponding invoices, including back-up documentation, in the specified currency, as described below. Undisputable invoices will be payable within **thirty (30) days** from the date of receipt by IQVIA of the invoice, including any applicable back-up documentation.

Invoices for any additional payments to those stated in this Agreement (i.e., additional reimbursements) must also be sent to IQVIA and approved by Sponsor. All invoices shall be raised in the following manner:

**Invoices to be billed and ORIGINAL copies to be sent to:**

**IQVIA RDS (India) Private Limited**

Omega Embassy Tech Square Marathahalli- Sarjapur Outer Ring Road, Kadubeesanahalli, Bangalore – 560102, Karnataka, India

**Invoices to be emailed to: scanned copy of the invoices to be emailed to:  
apac@ctp.solutions.iqvia.com**

The following information should be included on the invoice:

- Complete INVESTIGATOR name, address and phone number
- Invoice Date
- Invoice Number
- Payee Name (must match Payee indicated in CTA)
- Payment Amount
- Complete description of services rendered
- Study Number:
- Sponsor Name
- Invoices should be printed on Site/Institution letterhead

All invoice and payment related inquiries shall be addressed directly to the payments team at **apac@ctp.solutions.iqvia.com**.

Invoices and any accompanying documentation must not include any personally identifying information of any Study Subject, including but not limited to Study Subject first or last name, initials, date of birth, address, telephone, passport number, email address, or credit card information. If invoices or any accompanying documentation do contain this information IQVIA will notify Payee. Payee will need to resubmit a redacted invoice and accompanying documentation that does not include any personally identifying information of any Study Subject.

**NO OTHER ADDITIONAL FUNDING REQUESTS WILL BE CONSIDERED**

All amounts include all applicable taxes except GST.  
All payments for this Study will be  
paid by IQVIA electronically in accordance with Attachment A of this Agreement.

**ATTACHMENT B**  
**APPROVAL LETTER**



**Background**

- A On [insert date original agreement was signed], Novotech and **Mahatma Gandhi Mission Medical College & Hospital** entered into a Clinical Trial Agreement (**Agreement**) pursuant to which **Institution** provides clinical trial services to **SPONSOR (Services)** for Sponsor's clinical study (the "Study") with protocol no. "LYT-100-2022-204", Study Title "A Randomized, Double-blind, Four-Arm Active and Placebo-controlled Dose-Finding Trial to Evaluate the Efficacy, Tolerability, Safety and Dose Response of LYT-100 in Patients with Idiopathic Pulmonary Fibrosis (IPF)".
- B The parties agree to vary the terms of the Agreement as follows:
- The Per Subject Fee of the Agreement (being Page 13 to 19 inclusive of the Agreement) is deleted in its entirety and replaced with the Per Subject Budget table herein attached and marked as Annex A to reflect the updated costs due to Protocol version 5.0, date 26 Feb 2023 (Amended Protocol), the said costs will be effective to the date of the Independent Ethics Committee (IEC) approval of Amended Protocol in according with the Applicable.
- C The parties agree that all other terms of the Agreement remain the same.

*Base*

Novotech Variation Agreement


LYT-100-2022-204 Site 9104\_CTA Amend 1\_25 Jan 2024



**Executed as an Agreement**

Signed for and on behalf of **Novotech Clinical Research India Private Limited** by its authorised representative:

Signature

*Kanhaiya Choudhary*  


Name (print): **Kanhaiya Choudhary**

Title: **Director Clinical Operations**

Date: **31/JAN/2024**

Signed for and behalf of **Mahatma Gandhi Mission Medical College & Hospital** by its authorised representative:

Signature *[Signature]*

**Dr. Deepak Bhosle**  
Professor and Head  
Department of Pharmacology &  
Clinical Trial Center  
MGM MCH AURANGABAD

Name (print) **Dr. Deepak Bhosle**

Title **Prof. AMO, Dept of Pharmacology**

Date: **05/02/2024**

**Investigator: Dr Mohammad Hafiz Deshmukh.**

Signature *[Signature]*  
**05/02/2024**

**DR. HAFIZ DESHMUKH**  
ASSISTANT PROFESSOR  
DEPARTMENT OF RESPIRATORY MEDICINE  
MGM MEDICAL COLLEGE & HOSPITAL  
Aurangabad, Dist. N.S. 431007/120300

Name (print) *[Signature]*  
**Dr. Reemca Madhwar**

Title **Designated Partner**

Date: **05/feb/2024**

**Aurangabad Health Care & Research LLP**  
Shop No. 126, CTS No. 1243211, Chetan  
Trade Centre Opp. S.F. School, Jalna Road,  
Aurangabad.MH India.

*Base*

**Per Subject Fee**

All costs are exclusive of any applicable TAXES/GST (18%) and TAXES/GST of 18% shall be added and paid whenever any invoice is raised.

The CRO will pay INR **510900.00** (includes 30% IOH and local tax excluded) per subject who has completed the Part A of Clinical Trial and INR **586,625.00** per subject who has completed the Part B of Clinical Trial in accordance with the Protocol.

Such amount is divided as follows:

<b>Part A Visit Payment (INR) (Includes 30% IOH)</b>	
<b>Screening</b>	75075.00
<b>Baseline</b>	70200.00
<b>Visit 3</b>	53300.00
<b>Visit 4</b>	54600.00
<b>Visit 5</b>	49400.00
<b>Visit 6</b>	54600.00
<b>Visit 7</b>	49400.00
<b>Visit 8A</b>	68250.00
<b>Follow UP</b>	36075.00
<b>Total Per Patient Fee</b>	510900.00

<b>Part B Visit Payment (INR) (Includes 30% IOH)</b>	
<b>Visit 8B</b>	46,800.00
<b>Visit 9</b>	49,725.00
<b>Visit 10</b>	60,775.00
<b>Visit 11</b>	58,175.00
<b>Visit 12</b>	60,775.00
<b>Visit 13</b>	49,725.00
<b>Visit 14</b>	80,275.00
<b>Visit 15+</b>	69,225.00
<b>ET</b>	71,825.00
<b>Follow UP</b>	39,325.00
<b>Total Per Patient Fee</b>	586,625.00

The per patient fee above includes funds to reimburse the patient travel expenses, and also a **INR 5,000** per visit for patient participation fees. This will only be paid as approved by the applicable ethics committee.

A subject is considered as having completed the Clinical Trial when he/she has completed the specified Clinical Trial period and is evaluated per the Protocol.

In case of subjects included but not having completed the Clinical Trial, the amount to be paid will be calculated according to the fees for the visits actually performed by this subject. Where visits are conducted but not all per Protocol tests performed, the CRO reserves the right to withhold partial payment at its discretion. No payment will be made for an ineligible subject incorrectly enrolled into the Clinical Trial or in case the subject did not complete the Clinical Trial due to negligence, malpractice, breach of Protocol, or any willfully wrong act or omission on the part of the Investigator or Institution.

3 Screen Failures without a participant enrolled will be reimbursed, subsequent SFs will be based on the recruitment rate and at the approval of the Sponsor. Re-imbursement will be based on procedures that actual performed and against eCRF. For any Subjects that are randomized but are not administered



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*Kalija Jachy*

*[Signature]*

Clinical Trial Drug or that do not complete the study, site will be compensated for those procedures that have been performed, pursuant to the per-patient study budget.

The CRO will pay both the costs charged by the Independent Ethics Committee for review of the Protocol.

Central Laboratories will perform all pathology tests. All costs associated with the Central Laboratory, including courier charges, are borne separately by the CRO.

Unless otherwise agreed by the CRO in writing, the CRO will not be liable for any other payment other than those specified in this Agreement.

The parties estimate that the whole Clinical Trial will cost approximately INR 510900.00 for Part A and INR 586,625.00 for Part B (Includes 25% IOH) per patient (local tax excluded) assuming full enrolment by the Investigator of 5 completed Clinical Trial subjects.

#### Frequency of Payments

Routine payments will be made quarterly based on the CRF sections that have been completed, monitored and collected up until that time. It is expected that CRFs will be completed by the site within 7 days of a patient's visit.

A minimum of 30 days payment terms apply on receipt of invoice.

Two final quarterly invoices will be withheld for the payment until:

- the delivery of all CRFs, duly filled and revised and after the positive opinion on the part of the CRO regarding their filling;
- receipt of all responses to the data clarification forms (DCFs) from the Investigator;
- database lock has occurred;
- the Investigator has returned all remaining Investigational Product;
- return and receipt of all essential documents from the Investigator;
- the IEC has been informed of Clinical Trial closure by the Investigator;
- return and receipt of CRO equipment from the Investigator.

#### Method of Payment

(please tick one box)

- Please make payment by cheque.

Payee Name : \_\_\_\_\_ OR

- Please make payments via Electronic Funds Transfer (EFT).

**Payee Name:** Aurangabad Health Care & Research LLP

**Beneficiary Bank Account Number:** 50516370521

**Bank Name:** Indian Bank

**Bank Address:** Indian Bank, Chetan Trade Center, Opp.S.F. School, Jalna Road, Aurangabad,431001, Maharashtra, India.

**IFSC Code:** IDIB000A678

**GST No.:** 27ABRFA2186R1ZJ

**PAN No.:** ABRFA2186R



*Bole*

*Kabir Chaudhary*

*Amal*

**Trial Name:** 012-2021\_Progressive Fibrosing Interstitial Lung Disease (PF-ILD)  
**Arm:** Standard Arm\_Post Award Update\_75th percentile\_16-Jun-2022  
**Project:** 012-2021\_Progressive Fibrosing Interstitial Lung Disease (PF-ILD)  
**Phase:** Phase III  
**Indication:** Idiopathic Fibrosing Alveolitis, Idiopathic Pulmonary Fibrosis, Interstitial Pulmonary Fibrosis, IPF  
**Part:** A

**Selected Activities:** 2346.15 per patient

Name	OH?	Total	Screen VI	Visit 2 (W0)	Visit 3 (W4)	Visit 4 (W8)	Visit 5 (W12)	Visit 6 (W16)	Visit 7 (W20)	Visit 8A (W26, E7)	R	Revised Total (USD) (Revised total cost USD*total quantity)	Revised Selected Cost (USD) (Revised selected cost THB/36.6)	Revised Selected cost (INR) *editable values
Informed Consent Process	Y	1.00	1.00									64.10	64.10	5,000.00
IRCT	Y	1.00	1.00									INV	INV	2,500.00
Handling CT scans, preparation and equipment	Y	1.00	1.00									32.05	32.05	
Demographic Information	Y	1.00	1.00									19.23	19.23	1,500.00
Initial History Only	Y	2.00	1.00	1.00								38.46	38.46	1,500.00
Inclusion/Exclusion Criteria	Y	2.00	1.00	1.00								64.10	64.10	2,500.00
Adverse Events Assessment	Y	9.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	259.62	28.85	2,250.00
Review Concomitant Medications	Y	9.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	259.62	28.85	2,250.00
Phys Exam & Vitals Only	Y	2.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	123.08	19.23	1,500.00
Pre-Visit w/ Vitals	Y	2.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	115.38	19.23	1,500.00
Blood Collect, Ship & Prep (for safety, PK (in all patients), serum and plasma biomarker samples)	Y	8.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	201.92	57.69	4,500.00
Urine Collection, Prep & Ship	Y	8.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	461.34	57.69	4,500.00
Dip Stick UA w/ Microscopy	Y	8.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	102.56	12.82	1,000.00
Cotinine test (urine)	Y	4.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	102.56	12.82	1,000.00
Healthcare Res Util Quest	Y	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	51.28	12.82	1,000.00
Spirometry	Y	6.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	102.56	12.82	1,000.00
ECG w/ Interpret. & Report	Y	3.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	230.77	38.46	3,000.00
K-BILD, EQ-5D and SGRQ	Y	3.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	115.38	38.46	3,000.00
Randomization	Y	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	38.46	38.46	1,000.00
Vital status assessment	Y	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	12.82	12.82	1,000.00
Compliance / drug accountability	Y	7.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	134.62	19.23	1,000.00
Trial medication termination	Y	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	12.82	12.82	1,000.00
<b>Per Patient Activity Totals:</b>		445.51	34750	28000	358.97	230.77	243.59	192.31	243.59	192.31	378.21	60.90	2,346.15	1,000.00
						18000	19000	15000	19000	19000	29500	4750		



*Kashyap Chakraborty* *Amal* *Sale*



Selected Other Direct Costs : 2692.31 per patient

Name	OH?	Total Quantity	Screen V1	Visit 2 (W0)	Visit 3 (W4)	Visit 4 (W8)	Visit 5 (W12)	Visit 6 (W16)	Visit 7 (W20)	Visit 8A (W26, ET)	RU	Revised Total (USD) [Revised total cost USD*total quantity]	Revised Selected Cost (USD) [Revised selected cost THB/36.6]	Revised Selected cost (INR) * editable values*
Administer 1st trial medication at	Y	1.00										38.46	38.46	3,000.00
Physician's Fees without Exam Costs	Y	9.00										1,153.85	128.21	10,000.00
Study Coordinator Fee Per Visit (Including data entry)	Y	9.00										923.08	102.56	8,000.00
Patient Daily Reimbursement (Meals & Travel)	Y	9.00										576.92	64.10	5,000.00
Per Patient Other Direct Cost Totals:			294.87	333.33	294.87	294.87	294.87	294.87	294.87	294.87	294.87	2,692.31		
Overall Patient Cost			23000	26000	23000	23000	23000	23000	23000	23000	23000	23000		

	Screening	Treatment								Discontinuation	Follow Up	Total
		Visit 1 (W0)	Visit 2 (W4)	Visit 3 (W8)	Visit 4 (W12)	Visit 5 (W16)	Visit 6 (W20)	Visit 7 (W26)	Visit 8A (W26, ET)			
Costs Charged with Overhead	57750.00	54000.00	41000.00	42000.00	38000.00	42000.00	38000.00	42000.00	38000.00	52500.00	27750.00	393000.00
Overhead at 30%	17325.00	16200.00	12300.00	12600.00	11400.00	12600.00	11400.00	12600.00	11400.00	15750.00	8325.00	117900.00
<b>Selected Cost Per Visit</b>	<b>75075.00</b>	<b>70200.00</b>	<b>53300.00</b>	<b>54600.00</b>	<b>49400.00</b>	<b>54600.00</b>	<b>49400.00</b>	<b>54600.00</b>	<b>49400.00</b>	<b>68250.00</b>	<b>36075.00</b>	<b>510900.00</b>



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*Sumit*

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**Selected Other Direct Costs : 222000 per patient**

Name	OH?	Total	Period 1										Period 2			Total	Unit cost (INR)
			Every 13 weeks										Every 13 weeks				
			8B	9*	10	11*	12	13*	14	15+	ET*	15+	ET*	ET*			
Dispensation of tablets for Part B	Y	5.00	1.00	211	239	274	295	323	365	456+	1.00	1.00	1.00	1.00	1.00	15,000.00	3,000.00
Physician's Fees without Exam Costs	Y	9.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	90,000.00	10,000.00
Study Coordinator Fee Per Visit	Y	9.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	72,000.00	8,000.00	
Patient Daily Reimbursement (Meals & Travel)	Y	9.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	45,000.00	5,000.00	
Per Patient Other Direct Cost Totals:			26,000.00	23,000.00	26,000.00	23,000.00	26,000.00	23,000.00	26,000.00	23,000.00	26,000.00	23,000.00	23,000.00	23,000.00	23,000.00	222,000.00	

*Kabir Jee Chaudhary*

**Overall Patient Cost**

Visit	Period 1										Period 2			Total
	Every 13 weeks										Every 13 weeks			
	8B	9*	10	11*	12	13*	14	15+	ET*	15+	ET*	ET*		
Week	26	30	34	39	42	46	52	65+	65+	65+	65+	65+	65+	
Day	183	211	239	274	295	323	365	456+	456+	456+	456+	456+	456+	
Costs Not Charged with Overhead	36,000.00	38,250.00	46,750.00	44,750.00	46,750.00	46,750.00	38,250.00	61,750.00	55,250.00	30,250.00	461,250.00			
Costs Charged with Overhead	10,800.00	11,475.00	14,025.00	13,425.00	14,025.00	11,475.00	18,525.00	15,975.00	16,575.00	16,575.00	135,375.00			
Overhead at 30%	46,800.00	49,725.00	60,775.00	58,175.00	60,775.00	49,725.00	80,275.00	69,225.00	71,825.00	39,325.00	596,625.00			
Selected Cost Per Visit														

**Table 2, Invoiceable Costs**

Name	Site Cost (INR)	30% OH
HRCT	8,000	2,400
Televisit fee	1,000	300
COVID-19 test	1,000	300
Screen failure	Per Invoice	Per Invoice
unscheduled visit	Per Invoice	Per Invoice

To be paid on actual procedures performed up to full cost of Screening Visit, plus applicable overhead (+ PI and SC time)

3 SFs without a participant enrolled will be reimbursed, subsequent SFs will be based on their recruitment rate and upon sponsor approval.

To be paid based on actual procedures performed, including PI time, SC time and patient transport reimbursement, plus applicable overhead fee.



**Table 3, Site Level Other Direct Costs**

Name	OH	Site Cost (INR)	30% OH	Total payment (INR)	Payment Frequency
Study Start-up Fee (one off)	Y	100,000	30,000	130,000	To be paid upon SIV
Study Close-out Fee	Y	50,000	15,000	65,000	To be paid upon IRB approval date of study termination report
Site Administrative fee (Telephone, Internet, Printing, Stationery, etc) (per month)	Y	3,000	900	3,900	To be paid upon SIV until COV
Calibration Syringe	N	45,000	N/A	45,000	Pass through cost, pay upon receipt of a valid invoice by the vendor
Archiving/per site (estimated for 25 years)	Y	333,333	99,999.90	433,332.90	<ul style="list-style-type: none"> <li>The Institution will archive all relevant records for 25 years after the completion of the study at Sponsor's expense.</li> <li>Document Archiving fee is based on actual inventory and invoice at the time of document storage to the Institution.</li> <li>Payment will be made after submission of study completion or termination letter and upon receipt of a valid invoice by the Institute.</li> </ul>

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*Kabir Jee Chaudhary*



*[Signature]*



**Mahatma Gandhi Mission's (MGM) Medical College & Hospital, N-6, Cidco, Aurangabad, Maharashtra 431003 referred as a Party-B (here in after referred to as the "Institution") on ONE PART.**

**SHREE CLINICAL SERVICES PVT LTD, registered under the companies act 1956 with its address at S.P Office Road, Kolhapur Circle, Belagavi-590016 Karnataka, India (here in after referred to as the "SMO") on ANOTHER PART**

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 appoints SHREE CLINICAL SERVICES PVT LTD Services As a site management organization on Exclusive basis for period of 10 years w.e.f 8<sup>st</sup> July 2024 to 7<sup>th</sup> July 2034. (Will be reviewed and updated accordingly)**

#### **OBLIGATIONS OF SHREE CLINICAL SERVICES:**

**SHREE CLINICAL SERVICES** is a site management Organization based in Belagavi, Karnataka providing end to end clinical research services to the Hospitals and Offers a complete range of Clinical Research in all therapeutic areas. We expertise in site Management Activities, Project Management, Medical Writing, Monitoring, Safety Reporting, Regulatory services, Potential Site selection, Faster patient Recruitment, Quality compliance & Maintenance, and Clinical Research Expertise in India.

**SHREE CLINICAL SERVICES** is desirous of working with Hospital for the purpose of conducting ICH-GCP complaint phase I-IV clinical trials for new drug & treatment.


**SHREE CLINICAL Services** shall play vital role in getting clinical trials to the hospital /Hospital from the sponsors and CROs and execute them in Hospital.

**SHREE CLINICAL Services** will manage study Operations and study services as directed by study protocol for the duration of the clinical trial.

**SHREE CLINICAL Services** will appoint a Clinical Research Coordinators (CRC)/existing site coordinator who will be a point of contact with Sponsor & CRO and ensure smooth conduct of trial at the site.

**SHREE CLINICAL Services** will appoint project manager (PM) who will be responsible to coordinate and over-see the progress and management of CRC activities & trial, ensure data quality, resolve screening, enrollment or general issue if any, follow up on post -monitoring action elements and study training as per needs and frequent discussion with investigator & sponsor / CRO on trial progress.

**SHREE CLINICAL SERVICES PVT LTD** will appoint Quality check (QC Experts) who will be responsible to ensure adherence to the protocol, regulatory requirements record keeping and retention.

  
**Dean**  
**MGM's Medical College**  
**Aurangabad.**  
**Dr. Deepak Bhosle**  
**Professor and Head**  
**Department of Pharmacology &**  
**Clinical Trial Center**  
**MGM MCH AURANGABAD**



Study co-ordination, project management and quality management will be done by SHREE CLINICAL services. SHREE CLINICAL SERVICES personnel, CRC, PM, QC Experts will assist PI and the Intuitions in all trial related activities.


SHREE CLINICAL SERVICES will bear all the administrative cost related to the various activities undertaken by PM, CRC or any other staff placed by SHREE CLINICAL Services which includes telecommunication, travel cost, training cost at various centers across India or abroad.

SHREE CLINICAL SERVICES will be exclusively conducting/managing all trial at the Hospital during the tenure of this agreement. This agreement will last for 10 (ten) years and can be renewed further on mutual agreement.

**Following activities will be carried out by appointed CRCs or Project Coordinators**

- ✓ Performing all the activities in strict adherence to the ICH-GCP guidelines, Schedule Y India GCP and Regulatory requirement.
- ✓ Preparation for site selection visit and Site Initiation Visit (SIV).
- ✓ Communication & follow up with IRB/IEC Submission and Approval.
- ✓ Accurate and complete documentation of relevant EC documentation.
- ✓ Regulatory documents Collection.
- ✓ Patient Identification for assigned study form OPD or Hospital Database.
- ✓ Maintenance and update of Trial Master File (TMF), site binders and relevant files.
- ✓ Preparation for site Monitoring Initiation Visit (SMV) and resolving all action items generated during Previous monitoring visits.
- ✓ Conduct Study according to International Conference of Harmonization (ICH) E6 and India Good Clinical Practice (GCP) regulation.
- ✓ Assisting Principal Investigator in administrating ICF and its procedures.
- ✓ Ensure protocol & applicable regulatory guidelines compliance and adherence.
- ✓ Patients pre- screening enrollment and recruitment.
- ✓ Preparing source notes and CRF filling.
- ✓ Communication with CRA/ Project Manager, PI, IRB/IEC, site for study updates.
- ✓ Coordinate and schedule subject's regular follow up visits and procedures, maintain regular Telephonic contact with patients to preventing lost to follow- up and missed visits.
- ✓ Managing Clinical Trial Materials (CTM) maintenance, Accountability, distribution and logistics at site.
- ✓ Coordinate all site-specific queries- medical, administrative, subject reimbursements and other study Related activities.
- ✓ Reporting and coordinating all AE/SAEs according to their timelines as per regulatory norms.
- ✓ Filling up and maintaining trial related logs likes source documentation, drug dispensing logs, subject visit logs, Investigational product log, temperature log, SAE and EC communication log
- ✓ Documentation of protocol deviation as appropriate and communicate any impacting subject safety to the ethics committee.
- ✓ Coordinate with central and local lab for logistics and sample flow.
- ✓ Attend study related meeting as appropriate.
- ✓ Preparing sites for Monitoring / Auditing visits coordinate close out visit and Archival at site
- ✓ Any other required activities during the trials.

  
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- ✓ Identification of potential database from different therapeutic area of PIs.
- ✓ Communication with Investigators/ Hospitals and conduct protocol specific feasibilities.
- ✓ Other duties as requested by SHREE CLINICAL SERVICES PVT LTD Services Management

#### **B. Hospital permits**

- Hospital will give the space and required facilities to appointed CRC & SHREE CLINICAL SERVICES PVT LTD in order to perform clinical trials activities under respected PI.
- Hospital will allow SHREE CLINICAL SERVICES PVT LTD and Sponsors of Clinical trials to access the facility to verify source documents.
- Hospital will allow SHREE CLINICAL SERVICES PVT LTD to bring Sponsors of clinical trials to meet with PI/SITE representatives at a mutually convenient time.
- Hospital shall permit SHREE CLINICAL SERVICES PVT LTD to exclusively manage all clinical trial commenced by SHREE CLINICAL SERVICES PVT LTD Services

#### **C. Term of Agreement**

The term of this Agreement shall be for a period of 10 years commencing on the effective date 08<sup>st</sup> July 2024. However, this Agreement shall be reviewed annually by both parties if needed.

#### **D. Relationship of the parties**


1. Hospital and SHREE CLINICAL SERVICES PVT LTD are independent parties. Both parties agree that their relationship is that of an independent contractor and not employer and employee.
2. Neither party shall have express or implied rights nor authority to assume or create any obligation or responsibility on behalf of or in the name of the other party by reason of this Agreement, except as provided in this Agreement.


#### **E. GCP, ICH and CFR compliance**

Hospital agrees to comply with International Conference of Harmonization & Good Clinical Practices (ICH-GCP) and all India regulations, CDSCO requirement and circulars there under.

#### **F. Confidentiality**

1. The parties here recognize and agree that due to the complex and competitive nature of the business, the confidential 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 SHREE CLINICAL SERVICES PVT LTD 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 SITE.
2. Hospital shall not disclose to any third party any and information about new studies received from SHREE CLINICAL SERVICES PVT LTD.

  
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**MGM MCH AURANGABAD**




## G. Indemnification


Hospital shall indemnify and hold harmless SHREE CLINICAL SERVICES PVT LTD against any losses, claims, liabilities, damages and expenses of any nature, directly or indirectly arising out of any act or omission by SITE, its agents, directors or employees, SHREE CLINICAL SERVICES PVT LTD shall indemnify and hold harmless hospital against any and all losses, claims, liabilities, damages and expenses of any nature, directly or indirectly arising out of act or commission by SHREE CLINICAL SERVICES PVT LTD, its agents, directors, or employees. In no event will either party be required to indemnify or hold harmless the other's negligence or gross negligence.

## H. Compensation and Agreement

1. The Hospital, principal Investigator, SHREE CLINICAL SERVICES PVT LTD Services and Sponsor and/or CRO will enter into a quadripartite clinical trial agreement before/at the time of placement of each trial at the Hospital.
2. All feasibilities and payments shall be routed through SHREE CLINICAL SERVICES PVT LTD and pricing while bidding for the trial shall be discussed mutually and final correspondence with the Sponsor/CRO also would be handled by SHREE CLINICAL SERVICES PVT LTD Services for smooth and hassle-free finalization of Clinical Trial Agreements.
3. Getting payment from sponsor and giving to Hospital and /or Investigator is the responsibility of SHREE CLINICAL SERVICES PVT LTD Services.
4. SHREE CLINICAL SERVICES PVT LTD will be payee name for all trial related payment.
5. All payment shall be due and payable to the hospital on actual work i.e. number of subject randomized or visits completed.
6. The payment of remuneration shall be after deduction of all taxes under applicable laws.
7. All invoices will be requested from the hospital for study payment and all study related payment will be done to MGM Medical College & Hospital, in a period of 15 working days after receiving the payment from the sponsor/CRO.
8. The details of study budget sharing in INR is as follow:
  - 100% study payment will be paid to SHREE CLINICAL SERVICES PVT LTD from Sponsor/CRO for each study.
  - 60% study payment will be paid to Hospital /Principal Investigator from SHREE CLINICAL SERVICES PVT LTD.
  - 40% study payment fees will be paid to SHREE CLINICAL SERVICES PVT LTD.
  - 100% CRC fees will be paid to SHREE CLINICAL SERVICES PVT LTD from sponsor /CRO.
  - Additional 30% Institutional overhead will be paid from SHREE CLINICAL SERVICES PVT LTD received from sponsor/CRO.
  - SHREE CLINICAL SERVICES PVT LTD will pay Lab Cost, subject Hospitalization, SAE Medical Management charges at actual basis to Hospital /Principal Investigator received from sponsor /CRO.

(Note: Hospital should provide dedicated working printer, stationary, Electricity, Working place, Internet connection facility to our study team.)

  
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**MGM MCH AURANGABAD**





**I. Termination of Agreement**

1. 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.

**J. Permission to use personal Information or Statement**

For good consideration, the undersigned authorizes SMO and its assigns to use, publish or reprint in whole or part any basic information about my identity, practice, and participation in clinical research including any specific details of my clinical research that do not conflict with a previously contacted privacy agreement.


The two parties shall consult with each other and mediate any disputes which may arise about the contact. If all attempts fail the two parties can appeal to the organization of arbitration in judicial court of the state, India.

SIGNED AND EXECUTED BY the "SCR"

SHREE CLINICAL SERVICES PVT LTD

THROUGH ITS AUTHORISED SIGNATORY

---


) For SHREE CLINICAL SERVICES  
PRIVATE LIMITED  
)   
DIRECTOR  
) Mr. Vishweshwar Jakati  
) Director, Shree Clinical Services Pvt Ltd.

SIGNED AND EXECUTED BY the "MGM"

Mahatma Gandhi Mission's (MGM) Medical College  
& Hospital


THROUGH ITS AUTHORISED SIGNATORY

---

) Dr. Deepak Bhosle  
Professor and Head  
Department of Pharmacology &  
Clinical Trial Center  
MGM MCH AURANGABAD  
)   
) Dr. Deepak Bhosle

Professor & Head  
Dept. Of Pharmacology &  
Clinical Trial Center.



  
29/07/2024  
Dean  
MGM's Medical College  
Aurangabad.  
Dr. Rajendra Bohra  
DEAN  
MGM medical college &  
Hospital.  
Aurangabad, Maharashtra,  
India.



**MEDICOVER  
HOSPITALS**

A UNIT OF SAHRUDAYA HEALTHCARE PVT LTD.

## MEMORANDUM OF UNDERSTANDING

Between

**MGM Medical College and hospital , Chhatrapati Sambhajinagar (Aurangabad)  
And**

**Medicover Hospitals, Chhatrapati Sambhajinagar (Aurangabad)**

**(A unit of Sahrudaya health care private limited)**

For

**Academic Purposes**

**This Memorandum of Understanding (MOU)** is made and entered into as of this 18<sup>th</sup> September 2024 by and between **MGM-ECRHS, MGM Medical College, Aurangabad,** hereinafter referred to as "Ethics Committee," and **Medicover Hospitals, Chhatrapati Sambhajinagar (Aurangabad)** hereinafter referred to as "Hospital."

### 1. Purpose

The purpose of this MOU is to establish a collaborative relationship between the Ethics Committee and the Medicover Hospital for the facilitation and oversight of academic activities. This includes ensuring ethical standards are maintained in all academic research, training, and related activities conducted within the hospital.

**A UNIT OF SAHRUDAYA HEALTHCARE PVT LTD.**

**Medicover Hospital, Near Chistiya Police Chowki, N-6, Cidco, Chhatrapati Sambhajinagar - 431003**

**24x7 HELPLINE- 040 - 6833 4455**



H-2022-0977  
June 16, 2022 - June 15, 2025



## **2. Scope of Collaboration**

The collaboration will encompass the following:

- Ethical review and approval of DNB-related research projects.
- Oversight of the ethical conduct of clinical studies and research undertaken by DNB candidates.
- Guidance on ethical issues encountered during DNB training and research.
- Regular monitoring and evaluation of ongoing DNB projects to ensure compliance with ethical standards.

## **3. Responsibilities of the Ethics Committee**

The Ethics Committee agrees to:

- Review and approve DNB-related research proposals in a timely manner.
- Ensure that all DNB research complies with national and international ethical standards.
- Provide ethical guidance and support to DNB candidates and faculty.
- Conduct periodic audits and monitoring of DNB research activities.
- Maintain confidentiality and integrity of research data and subject information.

## **4. Responsibilities of the Hospital**

The Hospital agrees to:

- Facilitate the submission of DNB research proposals to the Ethics Committee for review.
- Ensure that all DNB research and training activities adhere to the approved ethical guidelines.
- Provide necessary resources and support for the ethical conduct of DNB research.

- Allow access to facilities and patient data as required for approved DNB research, accordance with ethical standards and patient consent.
- Ensure that DNB candidates receive appropriate training on research ethics and the importance of ethical compliance.
- Submitting six monthly progress report and completion of study.
- Reporting SAE and AE to EC as per regulatory guidelines.

## **5. Mutual Agreements**

Both parties agree to:

- Collaborate in the development and implementation of ethical guidelines for DNB academic activities.
- Address and resolve any ethical issues or concerns that arise during the course of DNB research and training.
- Maintain open communication and regular meetings to discuss the progress of DNB academic activities and any ethical considerations.
- Respect the confidentiality of all research data and patient information involved in DNB projects.

## **6. Duration and Termination**

- This MOU will be effective from 18<sup>th</sup> September 2024 and will remain in force until 17<sup>th</sup> September 2027 unless terminated by either party with 90 days' written notice.
- Either party may terminate this MOU if the other party fails to comply with the terms and conditions outlined herein.

## 7. Amendments

- Any amendments to this MOU must be agreed upon in writing by both parties.

## 8. Dispute Resolution

- Any disputes arising from this MOU will be resolved through mutual discussions and negotiations between the parties.

## 9. Remuneration

- The Hospital agrees to compensate the Ethics Committee for its services in reviewing and monitoring DNB-related activities. The remuneration details are provided in **Annexure I.**

## 10. Legal Status

- This MOU is a legally binding document and serves as a statement of intent to work together in a spirit of cooperation for the DNB academic purposes and clinical trial projects

IN WITNESS WHEREOF, the parties have executed this MOU

Dr. Deepak Bhosle

Professor & Head

Department of pharmacology

MGM Medical College, Chhatrapati Sambhajinagar (Aurangabad)

Date: 18<sup>th</sup> Sept 2024

**Dr. Deepak Bhosle**  
**Professor and Head**  
**Department of Pharmacology &**  
**Clinical Trial Center**  
**MGM MCH AURANGABAD**



Dr. Rajendra Bohra

Dear

**MGM Medical College, Chhatrapati Sambhajanagar (Aurangabad)**

Date: 18<sup>th</sup> sept 2024



Dr Dipen Shah

Centre Head



**Medicover Hospitals, Chhatrapati Sambhajanagar**

Date: 18<sup>th</sup> sept 2024

Dr. Dipen Shah  
Professor and Head  
Department of Pharmacology  
Clinical Trial Center  
MGM Medical College  
Aurangabad

## Annexure I


### Remuneration Details

#### For academic EC fee structure

- **Review of Research Proposals:** Amount 10,000/-per proposal
- Duplicate Approval 1000 **excluding TDS and GST**
- Change in title of approval letter 1000 **excluding TDS and GST**
- Fine for late submission of six-monthly report 100 per day **excluding TDS and GST**

#### For clinical trial EC fee structure

- Initial review Fee 75000 **excluding TDS and GST**
- Expidited Review fee 85000 **excluding TDS and GST**
- Amendment 30000 **excluding TDS and GST**
- **Other Services:** As mutually agreed upo

  
Dr. Deepak Bhosle  
Professor & Head  
Department of pharmacology

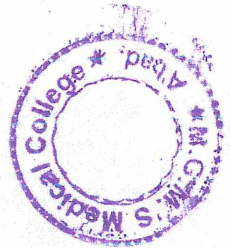
**Dr. Deepak Bhosle**  
**Professor and Head**  
**Department of Pharmacology &**  
**Clinical Trial Center**  
**MGM MCH AURANGABAD**

**MGM Medical College, Chhatrapati Sambhajinagar (Aurangabad)**

Date: 18th Sept 2024



*Handwritten signature and date: 20/9/24.*



Dr. Rajendra Bohra  
Dean

MGM Medical College, Chhatrapati Sambhajnagar (Aurangabad)

Date: 18<sup>th</sup> Sept 2024

*Handwritten signature of Dr. Dipen Shah.*

Dr Dipen Shah  
Centre Head



Medicover Hospitals, Chhatrapati Sambhajnagar (Aurangabad)

Date: 18<sup>th</sup> Sept 2024

*Handwritten signature of Dr. Deepak Bhaskar Bhosale.*  
Dr. Deepak Bhaskar Bhosale  
Professor and Head  
Department of Pharmacology & Toxicology  
Clinical Trial Center  
MGM S Medical College, Aurangabad

**Date: 19Aug2024**

Hafiz M Deshmukh  
MGM Medical College  
N-6, Cidco  
Aurangabad, Maharashtra, 431003  
India

Sponsor: BELLUS Health Cough Inc.  
Product: BLU-5937  
Protocol #: BUS-P3-01  
Site #: 291  
Visit Type: Site Visit Interim

Dear Dr. Hafiz M Deshmukh,

A Phase 3, 52-Week, Randomized, Double-Blind, Placebo-Controlled, Parallel-Arm Efficacy and Safety Study with Open Label Extension of BLU-5937 in Adult Participants with Refractory Chronic Cough, Including Unexplained Chronic Cough (CALM-1)

This is a confirmation letter for the upcoming 1st onsite monitoring visit scheduled on 20-Aug-2024. I have received confirmation from your site team for this visit.

I would appreciate your time to discuss questions and corrective actions raised during the visit. The remainder of the visit could take place with your study/research coordinator or designated staff member.

During the visit the following items will be reviewed:

- 1) Review of ICF for all screened subjects
- 2) Review of source data and eligibility for all screened & Randomized subjects
- 3) Review of eCRF for all screened subjects. Make sure all the data entry is done for screening and Randomization and for additional visit happened if any.
- 4) Review of study supplies and its validity.
- 5) Verification of IP storage and documentation
- 6) Review of ISF
- 7) Review of any AE's reported
- 8) Review of any PD's reported
- 9) Perform SDR and SDV for all Visit for randomized subject

Post review of data, I will meet investigator to discuss the outcome of the visit and about recruitment.

Mention if you have any challenges for conduct of study and let us know if any additional training required.

Please make sure the required staff is available at site and keep all the documents and subject files ready for the monitoring visit.

If you have any questions or are unsure about how to move forward with the action item, please contact me immediately for clarification at +918087844246 or via the email address below.

Please keep this letter filed in the Correspondence section of your Investigator Site File as applicable. Thank you and your team for your contribution to the study.

**Kind Regards,**

**Dhiraj Sarode**  
Clinical Monitor  
dhiraj.sarode@iqvia.com

**ESignature**

Signed By	Electronic Signature:	Date / Time signed:
	Dhiraj Sarode	19Aug2024 10:45:05 AM GMT

**cc: Trial Master File, IQVIA**

Recipients	
Hafiz M Deshmukh	dr.hafiz.deshmukh@gmail.com
Vikas Vetal	vikas.vetal@avacare.com



Dr Hafiz Deshmukh  
Mgm Medical College And Hospital, Aurangabad  
N-6  
Cidco. Aurangabad  
Maharashtra India

01-Aug-2024

**Re: LYT-100-2022-204**

**A RANDOMIZED, DOUBLE-BLIND, FOUR-ARM ACTIVE AND PLACEBO-CONTROLLED DOSE-FINDING TRIAL TO EVALUATE THE EFFICACY, TOLERABILITY, SAFETY AND DOSE RESPONSE OF LYT-100 IN PATIENTS WITH IDIOPATHIC PULMONARY FIBROSIS (IPF).**

**Site: 9104**

**Pre-visit letter to Monitoring Visit #6 on 05-Aug-2024**

Dear Dr. Deshmukh,

I hereby confirm my upcoming Monitoring Visit number #6 at your site on 05-Aug-2024. I plan to arrive at 10:00am and the visit will take approximately 07:30 hours. During the visit I will need to meet with you for about 15-20 minutes to discuss study updates, patient recruitment and any other important issues and obtain your signature on any relevant documents.

During this visit, I plan the following:

- Verify all newly signed Informed Consent Forms have been properly signed and that the Informed Consent process is documented in source records.
- Review new safety information to ensure all information has been reported to the PVG/Sponsor properly.
- Review CRFs and source documentation for  
9104-003: Visit10 and Visit11  
9104-007: Visit7, Visit8A and Visit8B.  
Please provide access to all required source documents and ensure all data is entered in eCRF, and all queries have been resolved.
- Review the inventory of study medication and study supplies.
- Review and update the Investigator Site File.
- Meet with you to discuss the enrollment plans and resolve any outstanding items.
- Visit applicable facilities.

In addition, please find below the list of outstanding Site issues/Action items to be resolved accordingly.

Issue date/ Submission date	Site issue	Action item	Deadline	Status	Comment
11-Dec-2023	For Sparse PK sample collections. Site is not storing the frozen back-up sample at site. site is shipping all	NA		Ongoing	



	samples to the lab on the same day.				
--	-------------------------------------	--	--	--	--

Please ensure the site team members delegated site staff, PI and Co-I will be available and have adequate time to review and discuss the items listed above.

Please feel free to contact me, should you have any questions. I look forward to meeting with you and your team soon.

Yours sincerely,

*Prachi Bulbule*

Electronically signed by: Prachi Bulbule  
Reason: I am the Author  
Date: Aug 1, 2024 22:31 GMT+5.5

Prachi Bulbule

Monitor

+91 9405114791

[Prachi.bulbule@novotech-cro.com](mailto:Prachi.bulbule@novotech-cro.com)







# LYT-100-2022-204\_9104\_#6RMV\_confirmation\_letter\_01-AUG-2024 (1)

Final Audit Report

2024-08-01

Created:	2024-08-01
By:	Prachi Bulbule (Prachi.Bulbule@novotech-cro.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAARwjj9n6UdPU2kuvToV6AuBuEUUo5n0AT

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-  Document created by Prachi Bulbule (Prachi.Bulbule@novotech-cro.com)  
2024-08-01 - 5:00:01 PM GMT- IP address: 117.99.253.209
-  Document emailed to Prachi Bulbule (Prachi.Bulbule@novotech-cro.com) for signature  
2024-08-01 - 5:00:31 PM GMT
-  Email viewed by Prachi Bulbule (Prachi.Bulbule@novotech-cro.com)  
2024-08-01 - 5:00:37 PM GMT- IP address: 20.92.77.202
-  Prachi Bulbule (Prachi.Bulbule@novotech-cro.com) authenticated with Adobe Acrobat Sign.  
Challenge: The user completed the signing ceremony.  
2024-08-01 - 5:01:15 PM GMT
-  Document e-signed by Prachi Bulbule (Prachi.Bulbule@novotech-cro.com)  
Signing reason: I am the Author  
Signature Date: 2024-08-01 - 5:01:17 PM GMT - Time Source: server- IP address: 117.99.253.209
-  Agreement completed.  
2024-08-01 - 5:01:17 PM GMT



Dr Hafiz Deshmukh  
Mgm Medical College And Hospital, Aurangabad  
N-6, Cidco  
Aurangabad. Maharashtra  
India

23-Oct-2024

**Re: LYT-100-2022-204**

**A RANDOMIZED, DOUBLE-BLIND, FOUR-ARM ACTIVE AND PLACEBO-CONTROLLED DOSE-FINDING TRIAL TO EVALUATE THE EFFICACY, TOLERABILITY, SAFETY AND DOSE RESPONSE OF LYT-100 IN PATIENTS WITH IDIOPATHIC PULMONARY FIBROSIS (IPF).**

**Site: 9104**

**Pre-visit letter to Monitoring Visit #7 on 25-Oct-2024**

Dear Dr. Deshmukh,

I hereby confirm my upcoming Monitoring Visit number #7 at your site on 25-Oct-2024. I plan to arrive at 10:00am and the visit will take approximately 07.30 hours. During the visit I will need to meet with you for about 15-20 minutes to discuss study updates, patient recruitment and any other important issues and obtain your signature on any relevant documents.

During this visit, I plan the following:

- Verify all newly signed Informed Consent Forms have been properly signed and that the Informed Consent process is documented in source records.
- Review new safety information to ensure all information has been reported to the PVG/Sponsor properly.
- Review CRFs and source documentation for  
9104-003: Visit12 and Visit13  
9104-007: Visit9 Pending pages and Visit10.
- Please provide access to all required source documents and ensure all data is entered in eCRF, and all queries have been resolved.
- Review the inventory of study medication and study supplies.
- Review and update the Investigator Site File.
- Meet with you to discuss the enrollment plans and resolve any outstanding items.
- Visit applicable facilities.
- In addition, please find below the list of outstanding Site issues/Action items to be resolved accordingly.

Issue date/ Submission date	Site issue	Action item	Deadline	Status	Comment
11-Dec-2023	For Sparse PK sample collections. Site is not	NA		Ongoing	



	storing the frozen back-up sample at site. site is shipping all samples to the lab on the same day.				
--	---	--	--	--	--

Please ensure the site team members will be available and have adequate time to review and discuss the items listed above.

Please feel free to contact me, should you have any questions. I look forward to meeting with you and your team soon.

Yours sincerely,

Prachi Bulbule  
Monitor  
[Prachi.bulbule@novotech-cro.com](mailto:Prachi.bulbule@novotech-cro.com)  
+91 94051147981

**Signature:** *Prachi Bulbule* Electronically signed by: Prachi Bulbule  
Reason: I am the Author  
Date: Oct 23, 2024 12:37 GMT+5.5  
**Email:** Prachi.Bulbule@novotech-cro.com









# LYT-100-2022-204\_9104\_#7RMV\_confirmation\_letter\_23-OCT-2024

Final Audit Report

2024-10-23

Created:	2024-10-23
By:	Prachi Bulbule (Prachi.Bulbule@novotech-cro.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAZkrxiZQiHcdhUqQ0-lheymZnbzg2J9vD

## "LYT-100-2022-204\_9104\_#7RMV\_confirmation\_letter\_23-OCT-2024" History

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-  Document emailed to Prachi Bulbule (Prachi.Bulbule@novotech-cro.com) for signature  
2024-10-23 - 5:45:55 AM GMT
-  Email viewed by Prachi Bulbule (Prachi.Bulbule@novotech-cro.com)  
2024-10-23 - 5:47:16 AM GMT- IP address: 20.70.11.189
-  Prachi Bulbule (Prachi.Bulbule@novotech-cro.com) authenticated with Adobe Acrobat Sign.  
Challenge: The user completed the signing ceremony.  
2024-10-23 - 7:07:09 AM GMT
-  Document e-signed by Prachi Bulbule (Prachi.Bulbule@novotech-cro.com)  
Signing reason: I am the Author  
Signature Date: 2024-10-23 - 7:07:15 AM GMT - Time Source: server- IP address: 136.226.232.124
-  Agreement completed.  
2024-10-23 - 7:07:15 AM GMT



Dr Hafiz Deshmukh  
Mgm Medical College And Hospital, Aurangabad  
N-6. Cidco  
Aurangabad. Maharashtra  
India

29-May-2024

**Re: LYT-100-2022-204**

**A RANDOMIZED, DOUBLE-BLIND, FOUR-ARM ACTIVE AND PLACEBO-CONTROLLED DOSE-FINDING TRIAL TO EVALUATE THE EFFICACY, TOLERABILITY, SAFETY AND DOSE RESPONSE OF LYT-100 IN PATIENTS WITH IDIOPATHIC PULMONARY FIBROSIS (IPF).**

**Site: 9104**

**Pre-visit letter to Monitoring Visit #5 on 05-Jun-2024**

Dear Dr. Deshmukh,

I hereby confirm my upcoming Monitoring Visit number #5 at your site on 05-Jun-2024. I plan to arrive at 10:00am and the visit will take approximately 07:30 hours. During the visit I will need to meet with you for about 15-20 minutes to discuss study updates, patient recruitment and any other important issues and obtain your signature on any relevant documents.

During this visit, I plan the following:

- Verify all newly signed Informed Consent Forms have been properly signed and that the Informed Consent process is documented in source records.
- Review new safety information to ensure all information has been reported to the PVG/Sponsor properly.
- Review CRFs and source documentation for  
9104-003: Visit8A, Visit8B, Visit9B  
9104-007: Visit4, Visit5, Visit6.  
Please provide access to all required source documents and ensure all data is entered in eCRF, and all queries have been resolved.
- Review the inventory of study medication and study supplies.
- Review and update the Investigator Site File.
- Meet with you to discuss the enrollment plans and resolve any outstanding items.
- Visit applicable facilities.

In addition, please find below the list of outstanding Site issues/Action items to be resolved accordingly.

Issue date/ Submission date	Site issue	Action item	Deadline	Status	Comment
11-Dec-2023	For Sparse PK sample collections. Site is not storing the frozen back-up sample at site. site is shipping all	NA		Ongoing	



	samples to the lab on the same day.				
26-Dec-2023	NA	Site need to retrain on the completion of the validated questionnaire.	22-Mar-2024	Ongoing	Retraining will be done on the next IMV. Telephonically site has been instructed on the same.

Please ensure the site team members delegated site staff, PI and Co-I will be available and have adequate time to review and discuss the items listed above.

Please feel free to contact me, should you have any questions. I look forward to meeting with you and your team soon.

Yours sincerely,

*Prachi Bulbule*

Electronically signed by: Prachi Bulbule  
Reason: I am the Author  
Date: May 31, 2024 12:51 GMT+5.5

Prachi Bulbule

Monitor

[Prachi.bulbule@novotech-cro.com](mailto:Prachi.bulbule@novotech-cro.com)

+91 9405114791.








# LYT-100-2022-204\_9104\_RMV#5\_confirmation\_letter\_29-MAY-2024

Final Audit Report

2024-05-31

Created:	2024-05-31
By:	Prachi Bulbule (Prachi.Bulbule@novotech-cro.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAANYhGI3tEo19b_AytCsUNAfcp_NWfKCfT

## "LYT-100-2022-204\_9104\_RMV#5\_confirmation\_letter\_29-MAY-2024" History

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-  Document emailed to Prachi Bulbule (Prachi.Bulbule@novotech-cro.com) for signature  
2024-05-31 - 7:18:27 AM GMT
-  Email viewed by Prachi Bulbule (Prachi.Bulbule@novotech-cro.com)  
2024-05-31 - 7:18:31 AM GMT- IP address: 20.28.41.198
-  Prachi Bulbule (Prachi.Bulbule@novotech-cro.com) authenticated with Adobe Acrobat Sign.  
Challenge: The user completed the signing ceremony.  
2024-05-31 - 7:20:47 AM GMT
-  Prachi Bulbule (Prachi.Bulbule@novotech-cro.com) has agreed to the terms of use and to do business electronically with NOVOTECH (AUSTRALIA) PTY LTD.  
2024-05-31 - 7:21:08 AM GMT- IP address: 106.193.235.52
-  Document e-signed by Prachi Bulbule (Prachi.Bulbule@novotech-cro.com)  
Signing reason: I am the Author  
Signature Date: 2024-05-31 - 7:21:08 AM GMT - Time Source: server- IP address: 106.193.235.52
-  Agreement completed.  
2024-05-31 - 7:21:08 AM GMT

**Date: 22 Nov 2024**

**To,**

**Dr. Ashish Deshmukh,**

MGM Medical College & Hospital,

Aurangabad, Maharashtra, India,

Pin code- 431003,

**Subject:** Site Selection Confirmation Letter (SCD-153-24-01)

Dear **Dr. Ashish Deshmukh,**

We are glad to inform you and your team that your site, MGM Medical College & Hospital, has been selected based on SQV conducted on 18 Nov 24, for our forthcoming study on “A Randomized, Double-Blind, Vehicle-Controlled Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Efficacy of Topically Applied SCD-153 in Patients with Alopecia Areata.” sponsored by Sun Pharma Advanced Research Company Limited Ltd, India. Site Identification no. is 119 for this particular study.

We will let you know about the further course of action as a part of study procedure.

In case of any clarification required, please feel free to contact me on **+91 9979945355** or [mdsharma@cliantha.com](mailto:mdsharma@cliantha.com)

Yours Sincerely,

**Dr. Manish Sharma,**

**Project Manager**

**Cliantha Research Limited - Ahmedabad**

cliantha<sup>®</sup>  
research



## SITE SELECTION LETTER

LRP/LUBT022/2024-12/114

DATE: 27-Dec-2024

To

**Dr. Ketan Shirsath,**

MGM Medical College and Hospital,

Gate No. 2, MGM Campus, n-6, CIDCO,

Chhatrapati Sambhajnagar (Aurangabad),

Maharashtra, 431003

Ref: **Protocol No.:** LRP/LUBT022/2024/002

**Protocol Title:** A randomized, double-blind, multi-center, active-control, parallel group study to compare efficacy, safety, immunogenicity and pharmacokinetics of Lupin's Nivolumab (LUBT022) with Innovator's Nivolumab in patients with locally advanced or metastatic non-small cell lung cancer

Dear Dr. Shirsath,

We are pleased to inform you that your site is selected for participation in the study listed in the title.

We look forward to working with you to achieve the study goals and will keep you informed on further study related activities.

We will contact you/site team soon for collecting essential study documents required for regulatory and ethics committee submission package.

We would like to thank you once again for your continued interest in the study and look forward to collaborating with you and your team soon. In case you have any further questions or wish to seek any clarification, please feel free to contact me at 9545040540 and [ankitavshelar@lupin.com](mailto:ankitavshelar@lupin.com).

Kind regards,

Signed by Ankita Shelar.  
Email: [ankitavshelar@lupin.com](mailto:ankitavshelar@lupin.com), Date: 27-Dec-2024 10:37 AM +05:30. D  
ocID: 16f1af5f-b1b3-4c3  
6-bd33-adc42e2af591.

Ankita Shelar

Clinical Research Associate

29 May 2024

Dr. Sudhir Kulkarni,  
MGM Medical College & Hospital,  
N-6, CIDCO,  
Aurangabad, Maharashtra, 431003

Re: **Protocol Number: WAL0921-02 Site Selection Letter**

**Protocol Title:** Phase 2 Safety and Efficacy of WAL0921 in Patients with Glomerular Kidney Diseases and Proteinuria

Dear Dr. Sudhir Kulkarni,

Congratulations on being selected to participate in the Walden Biosciences WAL0921-02 study! We look forward to working with you on this exciting and important new study. George Clinical is the CRO designated to provide services for and manage the study and will be working very closely with the Sponsor, Walden Biosciences for the duration of the study.

You will receive an email containing the essential study documents that will need to be completed by your site for the study and returned to George Clinical for site startup.

I will be your primary point of contact regarding any site startup questions and will be collecting copies of all essential and non-essential documents that are needed for the study. I will also oversee the conduct of the study and you may also contact me for any questions that may arise. My contact information is listed below.

Hiren N Barchha Principal Clinical Research Associate George Clinical, Plot No. 5, Prestige Khoday Towers, 12 <sup>th</sup> floor, Raj Bhavan Road Bangalore – 560001 / Karnataka / India <a href="mailto:hbarchha@georgeclinical.com">hbarchha@georgeclinical.com</a> M +91-9016782745
--

During our meeting, it was noted that the site currently lacks a -70°C deep freezer and a cold centrifuge. However, the feasibility assessment indicated that the site could procure (-70°C deep freezer) and could not procure cold centrifuge. I am in discussions with the internal team and will provide their feedback as soon as possible with regard to same.

We look forward to working with you on the WAL0921-02 study! Please contact us with any questions or comments and let us know if we can help in any way.

Kind regards,

Hiren N Barchha  
Principal Clinical Research Associate  
**cc: TMF**





Mahatma Gandhi Mission's

## **MGM Medical College**

N-6 CIDCO, Aurangabad - 431 003.

Ph-0240-6482000, Fax: 0240 2484445, 2487727

E Mail: mgmmca@themgmgroup.com

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### **MEMORANDUM OF UNDERSTANDING**

This MOU is with reference to the Agreement signed on the 27<sup>th</sup> day of August 2021 by and between **MGM Medical College & Hospital** incorporated under the laws of India & having its registered office at Gate No – 2, N-6 CIDCO, Aurangabad - 431003 represented through its authorized signatory Dean (hereinafter referred to as "MGM Emergency Medicine Department and MGM Medical Education and Skill development Unit")

**AND**

**Indian Red Cross Society**, a company incorporated under the laws of India & having its Aurangabad Branch office at 4, Sudhagauri Arcade, Rokdiya Hanuman Colony, Jalna Road, Aurangabad 431001 represented through its authorized signatory Mr. Sanjay Hiwarekar (Hereafter referred to as "INDIAN RED CROSS SOCIETY, Br. Aurangabad")

1. **Period of MOU:** Valid from date 27<sup>th</sup> day of August 2021 till either party terminates the MOU. MGM Emergency Medicine Department and MGM Medical Education and Skill development Unit may terminate this agreement at any time by giving 30 days written notice to the INDIAN RED CROSS SOCIETY Br. Aurangabad at its last known address. And INDIAN RED CROSS SOCIETY Br. Aurangabad can also terminate this agreement by giving 30 days written notice to the MGM Emergency Medicine Department and MGM Medical Education and Skill development Unit.
2. **Scope of Services:** For educational training and certification of COLS, First Aid and other life saving education in association with MGM Skill development Unit to industrial employees, general public with valid certification from RED CROSS.
3. **Remuneration:** MGM will pay Rs. 50/- per delegate / employees charges to be payable to RED CROSS SOCIETY BR, AURANGABAD against the services in clause no 2 by cheque
4. **MGM Emergency Medicine Department and MGM Medical Education and Skill development Unit** will share the necessary information regarding all activities conducted in association with INDIAN RED CROSS Br. Aurangabad, before and after the event at industry or public level with INDIAN RED CROSS Society Br. Aurangabad
5. **INDIAN RED CROSS SOCIETY, Br Aurangabad** can send the their representative at the event at their own cost and display the banner of Red cross along with Banner of MGM Medical college and Hospital, Aurangabad



Mahatma Gandhi Mission's

### MGM Medical College

N-6 CIDCO, Aurangabad - 431 003.  
Ph-0240-6482000, Fax: 0240 2484445, 2487727  
E Mail: mgmmca@themgmgroup.com

6. For all types of communications following are the details:

For MGM:

MGM Emergency Medicine Department and MGM Medical Education and Skill development Unit

E mail ID: metunitmgm@gmail.com

Phone No: 0240 6482000 Ext: 1063 / 1061





For Red Cross:

Mr. Prajwal Mithawala

E mail ID: lekh777@gmail.com

Cell No: 9422210659

IN WITNESS WHEREOF, the authorized representatives of the parties have hereinto set their hands upon the date first above written.

Signature :  DEAN MGM'S MEDICAL COLLEGE AURANGABAD	Signature :  INDIAN RED CROSS SOCIETY
Dr. Rajendra Bohra MGM Medical College & Hospital, Aurangabad.	Adv Mr. Sanjay Hiwarekar Aurangabad Branch Indian Red Cross Society, Branch Aurangabad
Title: Dean	Title : Chairman
Witness: 1. Sign:  2. Name: Dr Sadhana Kulkarni 3. Designation: Prof and HOD Emergency Medicine and Incharge skill Development	Witness: 1. Sign:  2. Name: Mr. Prajwal Mithawala 3. Designation: Secretary
Date: 27 <sup>th</sup> August 2021	Date: 27 <sup>th</sup> August 2021
Stamp <b>Dr. Sadhana Kulkarni</b> Professor and Head Department of Emergency Medicine MGM Medical College, Aurangabad.	Stamp <b>INDIAN RED CROSS SOCIETY</b> Aurangabad Branch



महाराष्ट्र MAHARASHTRA

2023

96AA 294732

कोषागार क्रमांक- 5739  
24 MAY 2024  
संतोषपूरनार दिडवाले  
स्टॅम्प वेंडर, औरंगाबाद  
परवाना क्र.3101057

28 MAY 2024

Prakash Bhagaji Sule  
Yashodha Ganesh Sule (MGM Medical College & Hospital Aurangabad)

MEMORANDUM OF UNDERSTANDING

BETWEEN

M/S INDIAN RESUSCITATION COUNCIL FEDERATION

through its Chairman, Dr. Siddha SC Chakra Rao, son of Sri Narayana Murthy, having its Registered Headquarter office at D.No.3-16B-100/1, Shanti Nagar, Kakinada, Andhra Pradesh -533003

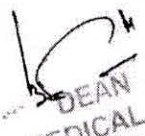
AND

MEMORANDUM OF UNDERSTANDING THIS MEMORANDUM OF UNDERSTANDING ("MOU") is made on ..... Date:..... at

DEAN  
MGM'S MEDICAL COLLEGE  
AURANGABAD

Place Skill lab MGM Medical by College Aurangabad .....and between:

**M/S Indian Resuscitation Council Federation** registered under the companies Act, 2013 (18 of 2013) through its Chairman, Dr. Siddha SC Chakra Rao, son of Sri Narayana Murthy, having its Registered Headquarter office at D.No.3-16B-100/1, Shanti Nagar, Kakinada, Andhra Pradesh -533003 (hereinafter referred the "IRCF" which expression, unless repugnant to the context or meaning thereof, shall include its successors and permitted assigns); the First Party AND MGM Medical college & Hospital Aurangabad.....the Second Party are hereinafter collectively referred to as the "Parties" and individually as a "Party", as the context may require. WHEREAS the First Party 'IRCF' a registered NGO under companies act, is independent body comprised of many other organisations who work with similar aims and objectives. AND WHEREAS the First Party, Indian Resuscitation Council Federation, hereafter called 'IRCF' has represented to have developed and prepared the Indian Resuscitation Guidelines, which were peer reviewed and published in an indexed journal; Indian Journal of Anaesthesia. The Second Party approached the First Party to establish Comprehensive Resuscitation Training Centre at Skill lab MGM Medical college Aurangabad with the interest of training all the interested citizens came into contact with the Second Party, in accordance with the IRCF guidelines on the following terms and conditions:

  
DEAN  
MGM'S MEDICAL COLLEGE  
- AURANGABAD

## **Terms and Conditions:**

### **1. Period:**

The period of MOU shall be Two Years and can be renewed, which will commence from the date of execution of this Memorandum of Understanding.

### **2. Fees:**

a) **Registration fee** - The charges for granting the CRTC will be ₹ 3000/- at the time of registering CRTC and renewal charges will be ₹ 2000/- every two years. However, institutions like Medical and Nursing Colleges will be exempted from the initial registration fee but have to pay the renewal fee. As per this clause the Second Party is exempted from the registration fee as it is already an established nursing college.

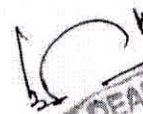
b) **Renewal fees** - If Second Party conducts training of minimum 150 students of BCLS training per year, the renewal charges will be waived off. This clause will come to effect from day of the first training initiated by the First party. The duration of the first year will be counted from the day of the first training done.

3. The Second Party has agreed to abide by the applicable norms prescribed in the First party website [www.cprindia.in](http://www.cprindia.in) to establish a CRT Centre with the permission of First Party; IRCF with the required equipment and instructors. The second party shall strictly adhere to and respect the applicable terms and conditions of training.


4. The Second Party shall extend co-operation by coordination for proper implementation of the training programme which is utmost necessary for the public interest.

5. The First Party shall, as the facilitating agency, monitor and guide the Second Party for ensuring its sustainability on principles of unity, self-help, and mutual co-operation among them for achieving their social and health empowerment objectives.

6. The First Party may depute an observer to inspect the premises of Second Party and other requirements before according permission.


  
DEAN  
MGM'S MEDICAL COLLEGE  
AURANGABAD

7. The First Party will conduct Training of Trainers (TOT) programme to train instructors, who are interested and well experienced in the field. The second party has to bear the travel, hospitality and a remuneration of ₹5000/- to the instructors or the inspector or observer.
8. The Second Party has specifically agreed to teach only in accordance with the Indian Resuscitation Council Federation guidelines which will be updated from time to time.
9. The Second Party should obtain the teaching manuals from the First Party only on paying the costs incurred thereof which will be decided from time to time. The second party shall not indulge in the practice of copying them by electronic or physical means.
10. The Second Party should not mix the Resuscitation guidelines of Indian Resuscitation Council Federation with the guidelines of any other country or organisation.
11. For every session of training, the Second Party shall get from the First Party the training manuals, one for each candidate and conduct the training as per the norms fixed hitherto.
12. The Second Party shall have to pay ₹550/- for BCLS manuals and ₹ 1000/- for CCLS manuals including the GST, towards the cost of material supplied which may be changed as per the cost of printing in form of manuals and the examination conducted and evaluated by the First Party per candidate they plan to train. This amount will be decided from time to time.
13. The Second Party shall get the renewal of the training programme once every two years on payment of prescribed nominal renewal fee to the First Party, as per point 2b.
14. The Second Party shall conduct all the necessary tests like screening of all the trainees for temperature, observing social distancing, wearing masks, using sanitizers

  
DEAN  
MGM'S MEDICAL COLLEGE  
AURANGABAD

etc., and follow all the other safety measures of COVID-19 era during the pandemic as mandated by the Govt. from time to time.

15. The First Party is not at all responsible for any mishaps or any other untoward incident or accident that may happen which amounts to injury, any other infliction or death of any individual during the said training.
16. The Second Party, CRTTC, may have to obtain an insurance policy for the trainees during the course of the training.
17. The Second Party shall ordinarily appoint instructors and intimate the First Party about the address and details of their office and training centre, the name, mobile number, e-mail id and validity of their Training certificate of the instructors for every workshop.
18. The Second Party will not normally deviate from the guidelines of the First Party.
19. The First Party shall send the observer to the Second Party for making the inspection at regular intervals.
20. The periodical inspection may be either to observe the training programme online or the observer may physically be present.
21. The Second Party shall bear all the costs of reasonable hospitality and travelling expenses by suitable means and remuneration for the observer as prescribed.
22. The Second Party shall have to purchase all the required equipment suggested by the First Party, IRCF, from the company of Second Party choice under the guidance of the First Party.
23. The First Party shall conduct examinations for the trainees of the Second Party on completion of the training programme and issue Certificate for the training undergone under their guidance, to its satisfaction. The candidates who are not successful after the examination conducted for the purpose shall have to appear for training again.


  
DEAN  
MGM'S MEDICAL COLLEGE  
AURANGABAD

24. The Second Party has agreed to abide by all the terms and conditions fixed between the Parties.

25. The First Party shall have all the rights to terminate the MOU with the Second Party with 30 days prior Notice providing opportunity to make good of the alleged breach if any, in case the Second Party violates any one of the terms and conditions here-in-after referred above without giving any notice .

26. The First party shall not hold any responsibility for the commissions and omissions of the certified candidates after training. The candidates have to observe and follow all the prevailing rules and Acts of Govt. of India.

27. Any dispute, controversy or claim between the Parties hereto arising out of or in connection with this Agreement including any question regarding its existence, validity, interpretation, breach or termination, or any default of any obligation hereunder, during the Term, hereof, shall be settled amicably failing which may be referred to be finally settled by arbitration in accordance with the Indian Arbitration and Conciliation Act, 1996 and the rules framed thereunder, as amended from time to time. The arbitration proceedings shall be conducted by a sole arbitrator, the parties hereby agree for the Arbitrator to be appointed from the panel of arbitrators maintained by the second party, the venue and seat of arbitration shall be at Kakinada jurisdiction only and the arbitration proceedings shall be conducted in the English language only.

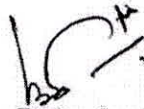
  
DEAN  
MGM'S MEDICAL COLLEGE  
AURANGABAD



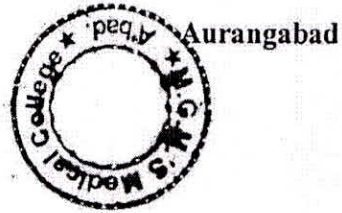
**IN WITNESS WHEREOF**, the Parties have caused this MOU to be executed as of the date first written above.

**For 1st Party**  
**M/S Indian Resuscitation Council Federation**


**For 2nd Party**

  
**Dr. Rajendra Bohra**  
**Dean**

**MGM Medical College and Hospital**



**Email ID Of CRTIC Coordinator: Dr. Sadhana Kulkarni Incharge of Skill Lab**  
**Email ID: [kulkarnisadhana@yahoo.com](mailto:kulkarnisadhana@yahoo.com), [skilllab@mghmcha.org](mailto:skilllab@mghmcha.org)**  
**Mobile Number of Coordinator: 9763350977**

  
**Dr. Sadhana S. Kulkarni**  
**Incharge Skill Lab**  
**MGM Medical College, N-6 CIDCO,**  
**Aurangabad**



Mahatma Gandhi Mission

## Medical College & Hospital

Sector – 1, Kamothe, Navi Mumbai – 410 209.

Tel No: 022-27432471, 27432994, Fax No: 022-27431094

Ref. No.: MGM/MEDC/SL/2023/

Date: 08<sup>th</sup> February 2023

### DEPARTMENT OF SKILLS LAB

To,  
The Dean,  
MGM Medical College and Hospital,  
Aurangabad.

Subject: AHA India Summit March 2023

Respected Sir,

As per the attached email from Dr Sachin Menon, Consultant Regional Director, AHA has requested to participate the instructor's & coordinator's in "AHA India Summit March 2023"

As MGM Aurangabad is now aligned as a "Training Site" with MGM Navi Mumbai, this is request you to kindly provide 3 instructor nominations for March 19 & 20, 2023.

With regards.

Dr Vishwas Sathe  
AHA Regional Faculty  
Incharge- MGM Skills Lab

INCHARGE  
MGM SKILLS LAB  
DATE: 10 / 02 / 23

## AHA India Summit March 2023

1 message

**Sachin Menon (Consultant)** <sachin.menon.consultant@heart.org>

Mon, Jan 9, 2023 at 11:46 AM

To: "Sachin Menon (Consultant)" <sachin.menon.consultant@heart.org>

Cc: "Srimon AK (Consultant)" <t-Srimon.AK@heart.org>, AHA ECC India Operations <aha.eccindia@gmail.com>

Dear TCCs:

Greetings!!!!

Hope you are having a happy and fruitful New Year full of peace, happiness, and prosperity!

It's been a challenging couple of years for all of us with all our virtual meetings. As a kick-off for the new initiatives to implement quality in our training, we initiated the TCF course in Mumbai in 2022, in conjunction with the Regional Faculty meeting.

To continue with this engagement, we cordially invite you to the **first AHA India Summit 2023**, which will take place from March 19th to March 24th, 2023 at Calicut, Kerala.

The event will be organised by the American Heart Association in association with the Aster MIMS Hospital, Calicut.

The Summit will feature a range of engaging instructional, administrative, and scientific presentations. There will also be an emphasis on a variety of interactive sessions, with an opportunity to engage with experts from US and India, as we have invited speakers from the disciplines of science and administration of the AHA. It will be an excellent opportunity to learn and network with your peers and experts in the field of resuscitation.

The day plans for the event is as provided below:

**To be organised by the AHA:**

Day 1 (19 March 2023) – AHA Instructor Update 2023 (**Instructors deputed by the ITC to attend – 5 persons per ITC**)

Day 2 (20 March 2023) – AHA Training Centre Coordinator Meeting 2023 (**TCC and the administrative staff only – 3 persons per ITC**)

Day 3 (21 March 2023) – AHA Regional Faculty Meeting 2023 (**Only by individual invite to the Regional Faculties**)

**To be organised by the Aster MIMS, Calicut:**

Day 4 (22 March 2023) – AHA BLS TCF Course

Day 5 (23 March 2023) – AHA ACLS TCF Course

Day 6 (24 March 2023) - AHA PALS TCF Course

(For MGM Aurangabad)  
to attend Day ① & ② only.  
[Signature]

The first 3 days will be offered to the training network without any registration fees as this is the first such event. But kindly register at the earliest as the seats are limited in number and registration will be on first come and first served basis. The attendance at this event will be counted towards the Instructor updates during the quality audits.

The TCF course fees will be as per the norms decided by the Aster MIMS Hospital.

We will provide you with the registration forms for the first 2 day's events and further information about the event, including the contact person, travel desk, and any other assistance you may require, in the next few days.

Details regarding each day's programme and venue will be shared with you shortly.

We are excited to see you all in Calicut.

Thanks and Regards,

# Prof. Dr. Sachin Menon MD, FICM

Consultant Regional Director (India, SL, Nepal & Bangladesh)

**American Heart Association, Inc.**



M. +91 9496906684

E. sachin.menon.consultant@  
heart.org

W. [www.international.heart.org](http://www.international.heart.org)

A. SS Associates, Souparnika, Chittoor Mana Rd, P.O. Cherpu, Thrissur,  
Kerala, India - 680561

LEGAL NOTICE: This electronic message and any attachments transmitted with it may contain confidential information intended only for the named recipient. Any use, distribution, copying or disclosure of this communication is strictly prohibited. This electronic message does not constitute a binding agreement on behalf of American Heart Association (AHA) with another party without confirmation by the AHA Legal Department. If you have received this e-mail in error, please notify the sender by reply e-mail, and delete all copies of this communication from your computer and network. Thank you.



Mahatma Gandhi Mission  
**Medical College & Hospital**  
Sector - 1, Kamothe, Navi Mumbai - 410 209.  
Tel No: 022-27437900-200, 022-27433404

Date: 01/11/2023

**Memorandum of Understanding (MOU)**

Between

**MGM Medical College and Hospital, Kamothe, Navi Mumbai**

&

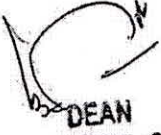
**MGM Medical College, Aurangabad**

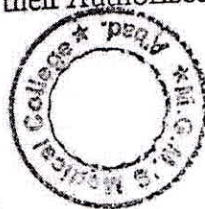
THIS Memorandum of Understanding is made on this 01 November 2023.

MGM Medical College & Hospital, Navi Mumbai (ITC- International Training Center for American Heart Association (AHA)), having registered office at Sector : 1 & 2, Kamothe, Navi Mumbai 410209, hereinafter called MGMMCH (which term shall deemed to mean and include its successor-in-interest, permitted assign, agents and executors) through their Authorized signatory.

AND

MGM Medical College, Aurangabad (TS- Training Site for American Heart Association (AHA). having its registered office at N6, CIDCO, Aurangabad, Maharashtra, owned by same MGM Trust hereinafter called "MGMMCA" (which term shall deemed to mean and include its successor-in-interest, permitted assign, agents and executors) through their Authorized signatory.

  
DEAN  
MGM'S MEDICAL COLLEGE  
AURANGABAD




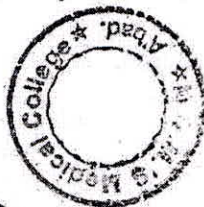
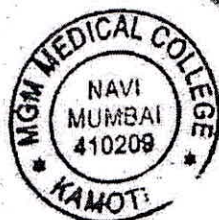
  
Dean  
MGM Medical College & Hospital  
Kamothe, Navi Mumbai-410209


NOW THEREFORE THIS AGREEMENT WITNESSETH:

Terms of MOU :

1. Candidate course fees will be decided & collected at MGM, Aurangabad
2. All the expenses borne during the course will be taken care by MGM, Aurangabad.
3. Roster locking & eCards generation will be done at MGM, Navi Mumbai (ITC).
4. MGM Aurangabad will pay (per delegate) to ITC as mentioned below:
  - a. Heart code BLS Provider Course e Card: Rs. 353/\*\*-per delegate (Rates will be at actual which may increase or decrease as quoted by AHA vendor).
  - b. ACLS Provider Course eCard: Rs. 631/\*\*- per delegate (Rates will be at actual which may increase or decrease as quoted by AHA vendor).
  - c. BLS Instructor e card Rs. 370/- per delegate (Rates will be at actual which may increase or decrease as quoted by AHA vendor).
  - d. ACLS Provider Course eCard: Rs. 685/\*\*- per delegate (Rates will be at actual which may increase or decrease as quoted by AHA Vendor).
5. First five courses (2 physically & 3 Online) will be supervised by AHA Course Director- Dr Vishwas Sathe & AHA ITC coordinator Mr. Nitesh Kadam. The first two courses will be conducted by faculties parent ITC from MGM Navi Mumbai along with faculties from Aurangabad. Travel & stay of the visiting faculty & AHA coordinator will be responsibility of MGM Aurangabad. After satisfactory conduction of the first five courses further courses will be conducted by MGM Aurangabad independently (online support via zoom or any other platform will be provided as required).

  
DEAN  
MGM'S MEDICAL COLLEGE  
AURANGABAD



  
Dean  
MGM Medical College & Hospital  
Kamot, Navi Mumbai-410209

6. As required by AHA, initially Mr. Nitesh will visit Thrice in a year & Dr Vishwas Sathe will visit Twice in a year at MGM Aurangabad Training Site for routine audit. Their travel & hospitality will be taken care by MGM, Aurangabad.

Disclaimer:

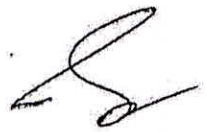
The American Heart Association strongly promote knowledge and proficiency in all AHA courses and has developed instructional materials for this purpose. Use of the material in and educational course, does not represent course sponsorship by the AHA. Any fees charged for such a course except for a portion of fees needed for AHA course material, do not represent income to AHA.

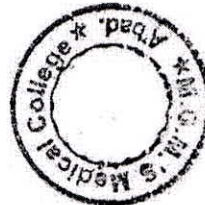
MGM Medical College & Hospital, Navi Mumbai (MGMMCH)

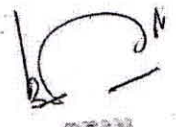
Address : MGM Medical College & Hospital, Kamothe, Navi Mumbai 410209

MGM Medical College, Aurangabad (MGMMCA)

Address : N6, CIDCO, Aurangabad, Maharashtra.

  
Dean  
MGM Medical College & Hospital  
Kamothe, Navi Mumbai-410209



  
DEAN  
MGM'S MEDICAL COLLEGE  
AURANGABAD



Mahatma Gandhi Mission

## Medical College & Hospital

Sector - 1, Kamothe, Navi Mumbai - 410 209.

Tel No: 022-27432471, 27432994, Fax No: 022-27431094

Ref. No.: MGM/MEDC/SL/2023/1339

Date: 13<sup>th</sup> October 2023

### DEPARTMENT OF SKILLS LAB

To,  
The Dean  
MGM Medical College & Hospital  
Sector - 1, Kamothe  
Navi Mumbai - 410 209.

**Subject:** MGMMC Navi Mumbai & MGM Aurangabad MOU for AHA Training Site

Sir

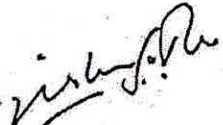
MGM Medical College & Hospital Navi Mumbai is an American Heart Association (AHA) Accredited ITC since 2018. We have conducted total 44 AHA BLS & ACLS Provider & Instructor Courses since 2018 and trained around 1306 students.

We have created **MGM Medical College & Hospital Aurangabad** as a Training Site (TS) on AHA website & it's ID is "TSO5628".

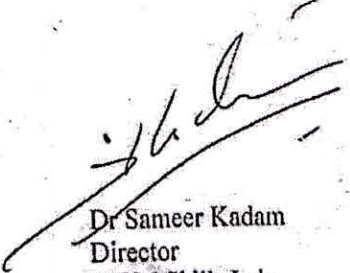
As per the AHA guidelines we have to prepare MOU between AHA training center (TC) MGM Navi Mumbai & AHA training site (TS) MGM Aurangabad. Enclosing herewith the draft of the MOU & requesting your permission & approval for the same.

Kindly do the needful.

Thanking you.

  
Dr Vishwas Sathe  
In Charge  
MGM Skills Lab

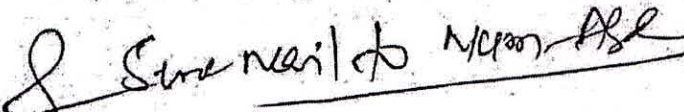
INCHARGE  
MGM SKILLS LAB  
DATE: 13/10/23  
Encl.: MOU draft

  
Dr Sameer Kadam  
Director  
MGM Skills Lab

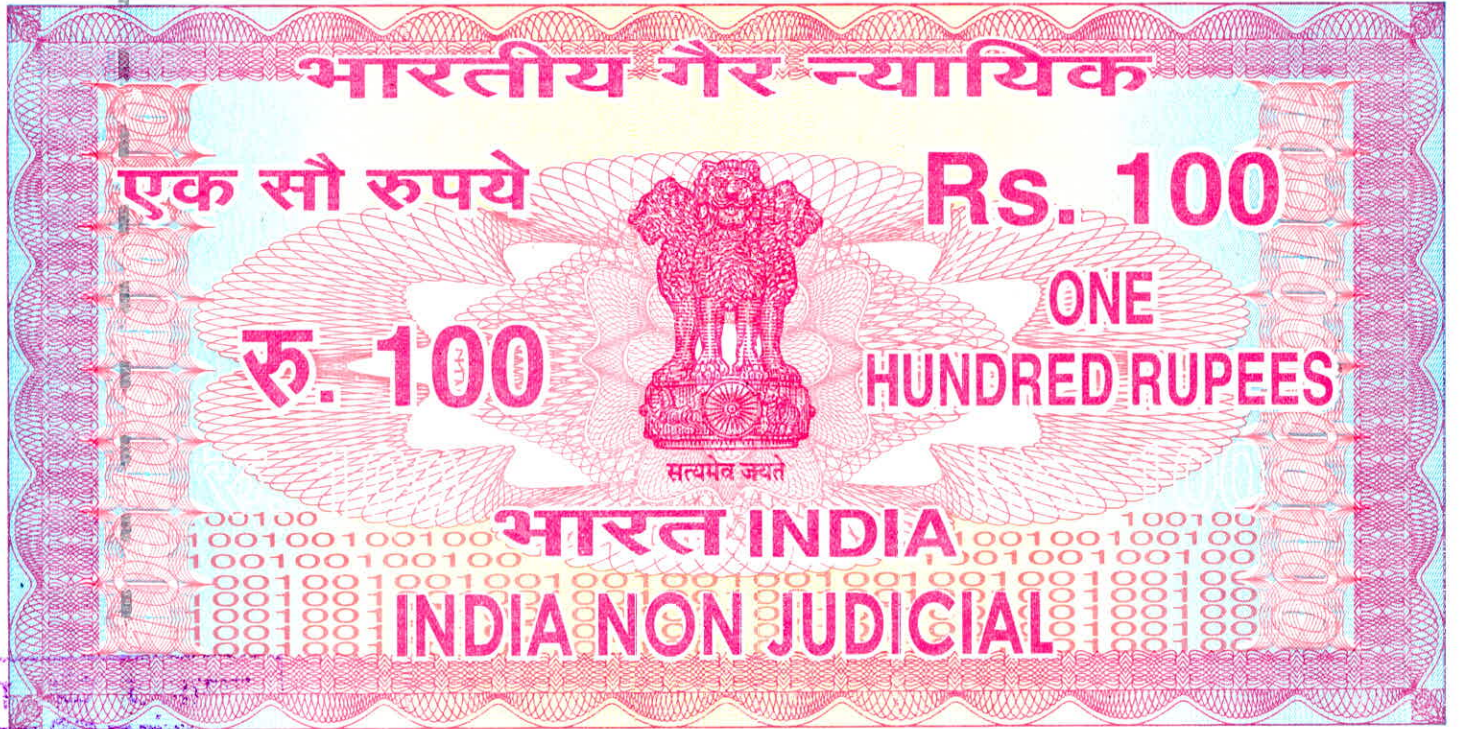
DIRECTOR  
MGM SKILLS LAB  
DATE: 13/10/23

approval

  
DEAN  
MGM'S MEDICAL COLLEGE  
AURANGABAD

  
Sameer Kadam





जिल्हा  
कार्यालय  
महाराष्ट्र MAHARASHTRA  
22 MAR 2024  
मुद्रांक प्रमुख विभागात  
व.को.अ. छत्रपती संभाजीनगर

● 2023 ● 71AA 507520  
प्रमोद म. कुलकर्णी  
मुद्रांक दिलेता  
एन-६ रिकॉर्ड छ सभाजीनगर  
परवाना : 3101056  
MGM Mother Teresa  
Camp of Keshavnagar  
दिनांक ११/३/२४  
किंमत १४२  
कोणाकरिता  
बस्तो  
रामेश एस  
A.M.C.

**MEMORANDUM OF UNDERSTANDING**

This MOU is with reference to the Agreement signed on the 02<sup>nd</sup> day of April 2024 between MGM Medical College and Hospital incorporated under the laws of India and having its registered office at Gate No-2, N-6, CIDCO, Chh.Sambajinagar-431003 represented through its Authorised signatory Dean ("Hereafter referred to as MGM Medical Education and Skill development unit")

AND

MGM Mother Teresa College of Nursing, N-6, CIDCO, Chh.Sambajinagar-431003 represented through its Authorised signatory Principal Dr. Satishchandra T Buyite (Hereafter referred to as MGM Mother Teresa College of Nursing")

1. Period of MOU: Valid from date 02<sup>nd</sup> day of April 2024 till either party terminates the MOU. MGM Medical Education and Skill development unit may terminate this agreement at any time by giving 30 days return notice to the MGM Mother Teresa College of Nursing at its last known address. And MGM Mother Teresa College of Nursing can also terminate this agreement at any time by giving 30 days return notice to MGM Medical Education and Skill development unit.

2. Scope of Service: For educational training and certification of BLS in association with MGM Skill development unit to the students with valid certification
3. Remuneration: MGM Mother Teresa College of Nursing will pay Rs 100 per student
4. MGM Medical Education and Skill development unit will share the necessary information regarding all activities conducted with students
5. MGM Mother Teresa College of Nursing can send their students at the event at their own cost and display the banner of MGM Mother Teresa College of Nursing along with the banner of MGM Medical College and Hospital, Chh.Sambajinagar
6. For all types of communications following are the details:

For MGM Medical College:

MGM Medical Education and Skill development Unit

E mail ID: metunitmgm@gmail.com

Phone No: 0240 6482000 Ext: 1063/1061







For MGM Mother Teresa College of Nursing

Principal

E mail ID: principalconabad@gmail.com

Phone No: 0240 6482000 Ext: 3050/2900

IN WITNESS WHEREOF, the authorized representatives of the parties have hereinto set their hands upon the date first above written.

Signature: 	Signature: 
Dr. Rajendra Bohra MGM Medical College & Hospital, Chh.Sambajinagar.	Dr. Satishchandra Buyite MGM Mother Teresa College of Nursing, Chh. Sambajinagar.
Title: Dean	Title: Principal
Witness: 1. Sign:  2. Name: Ghatge Mohan P. 3. Designation: Administrative Officer	Witness: 1. Sign:  2. Name: Prerana Dangi 3. Designation: Admin - officer
Date: 02/04/2024	Date: 02/04/2024
Stamp 	Stamp 

भारतीय गैर न्यायिक

एक सौ रुपये

Rs. 100

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सत्यमेव जयते

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INDIA NON JUDICIAL

महाराष्ट्र MAHARASHTRA

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छत्रपती संभाजीनगर

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मुंबई विवेका

एन-6, रिकवरी चॅम्बर्स, सभाजीनगर

परवाना नं. 3101056

Dr. Sushil Singh  
AMC

MGM Mother Teresa

College of Nursing

### MEMORANDUM OF UNDERSTANDING

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E mail ID: metunitmgm@gmail.com

Phone No: 0240 6482000 Ext: 1063/1061

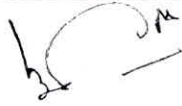

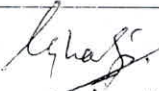

For MGM Mother Teresa College of Nursing

Principal

E mail ID: principalconabad@gmail.com

Phone No: 0240 6482000 Ext: 3050/2900

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Title: Dean	Title: Principal
Witness: 1. Sign:  2. Name: Ghatge Mohan P. 3. Designation: Administrative Officer	Witness: 1. Sign:  2. Name: Prerana Parvi 3. Designation: Admin-officer
Date: 02/04/2024	Date: 02/04/2024
Stamp DEAN MGM'S MEDICAL COLLEGE AURANGABAD	Stamp PRINCIPAL MGM'S MOTHER TERESA COLLEGE OF NURSING No.6, CIDCO, Chhatrapati Sambhajinagar