



# One Day Regional Training Programme for Admin Users of PDS (URKUND)

*Jointly Organized by*

**Mahatma Gandhi Mission Institute of Health Sciences, Navi Mumbai  
& INFLIBNET Centre, Gandhinagar, Gujarat**



**On:**

29<sup>th</sup> August, 2019

**Venue:**

Auditorium, 3<sup>rd</sup> Floor,  
Mahatma Gandhi Mission Institute of Health Sciences,  
Kamothe, Navi Mumbai



ज्ञान-विज्ञान विमुक्तये





## “One Day Regional Training Programme for Admin Users of PDS (URKUND)”

Jointly organized by  
Mahatma Gandhi Mission Institute of Health Sciences, Navi Mumbai  
& INFLIBNET Centre, Gandhinagar, Gujarat

On

29<sup>th</sup> August, 2019 (Thursday)

Programme Schedule

(09:30 to 17:30)

Sr. No.	Time	Program	Speakers
1.	08:30-09:15	<i>Registration</i>	
2.	09:15-09:25	Welcome Address by Registrar, MGMIHS	Dr. Rajesh B Goel
3	09:25-09:35	<i>Inauguration &amp; Felicitation of Dignitaries</i>	
4.	09:35-09:40	Address by MHRD /UGC	Representative
5.	09:40-09:45	Address by Chief Guest Hon'ble Vice Chancellor, MGMIHS	Dr. Shashank D.Dalvi
6.	09:45-09:55	Introduction to Ethics & Plagiarism by INFLIBNET	Mr. Manoj Kumar K
7	09:55-10:00	Vote of Thanks	Dr. Sabita M. Ram
8	10:00-10:30	<i>Group Photograph &amp; Tea Break</i>	
9	10:30-13:00	Introduction to URKUND Plagiarism Check	URKUND Team
10	13:00-13:30	<i>Lunch</i>	
11	13:30-16:30	Hands On/ Demo of PDS	URKUND Team
12	16:30-17:00	Discussion, Question Answer Session	URKUND Team
13	17:00-17:30	Summary & Feedback on Programme	Dr. Himanshu Gupta

For Registrations, please fill up the form available on the following link:

<https://forms.gle/aDrDMc2YjuoqkSYdA>







## For details contact:

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## MGM Institute of Health Sciences

(Deemed to be University established u/s 3 of UGC Act.)

**Grade 'A' Accredited By NAAC**

MGM Educational Campus,  
Sector 1, Kamothe,  
Navi Mumbai-410209,  
Maharashtra State (India)

Location Coordinates: 19.017412, 73.105131



**Report on One Day Regional Training Programme for Admin Users of PDS (URKUND)  
29<sup>th</sup> August, 2019 at MGM Institute of Health Sciences, Navi Mumbai.**

The Western Regional Training Programme on Plagiarism Detection Software was held at MGM Institute of Health Sciences, Navi Mumbai on 29<sup>th</sup> August, 2019. Delegates from Four States of Western Region of India, Gujarat, Rajasthan, Maharashtra, Goa and Karnataka participated in the workshop. A total no of 161 participants registered from 83 Universities and Institutions.

Dr. Sabita M Ram, Director (Research) was the organizer on behalf of MGM Institute of Health Sciences (MGMIHS) and Dr. Himanshu Guptawho was the Coordinator for the workshop.

It was an honor and privilege to have Shri. Gurinder S Malik, Senior Consultant, MHRD as the guest of honor and Mr. Manoj Kumar K from INFLIBNET as a speaker and honored guest. The Vice Chancellor Dr. Shashank D Dalvi and Registrar Dr. Rajesh B Goel of the MGM Institute of Health Sciences, presided over the function. The URKUND Team were the workshop conductors.

The program started with the inauguration with a houseful of participants. Dr. Rajesh B Goel, Registrar, MGMIHS welcomed the dignitaries and delegates to the MGMIHS for the workshop. He expressed the need to have such workshops to utilize and get familiar with the software. The Vice Chancellor emphasized the need to detect plagiarism and the research today must be more innovative and not copied from other researchers. One should be original in their research writing. Shri Gurinder S Malik appreciated the large number of participants. He made a point that the MHRD is taking up the project through INFLIBNET to stop plagiarism in a big way and all Universities/Institutes must be vigilant when research thesis of PhD and Research Publications are concerned and must have original Research writing. Mr. Manoj Kumar has brought about the need of a Software for detecting plagiarism, which would objectively detect plagiarism. URKUND that has been introduced for detection of Plagiarism has a number of features to Plagiarism detection.

The inauguration ended with a vote of thanks by Dr. Sabita M Ram. She acknowledged Shri. Gurinder S Malik for coming for the workshop. Mr. Manoj Kumar for helping to organizing the workshop.





The workshop started with Mr. Manoj Kumar K presentation of Introduction to Ethics & Plagiarism, which was very interesting and brought out the need to be ethical in research writing and if not the consequences of plagiarism. There was interaction amongst the speaker and participants to clarify their doubts.



URKUND Team Mr. Henin Sall presented the software and explained how it has been designed to detect plagiarism.

Mr. Prakash Sarda took a hands on training on the URKUND software programme, which was very interesting. The participants interacted enthusiastically and the session was informative and can be easily utilized for detection of plagiarism.

Mr. Manoj K Kumar, concluded the workshop taking queries and questions which he answered to the delegates satisfaction. The participants were requested to give a feed-back on the program through the google form. The feedback received from the participants was overwhelmed and was satisfied with the conduction of program. Few suggestions for increasing the time for hands on training was given.

Dr. Sabita M Ram, Director (Research), thanked one and all and handed over the Participation certificates.

MGM IHS, would like to thank INFLIBNET for the opportunity to conduct the regional level PDS workshop at our Institute.

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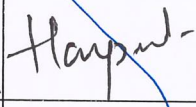



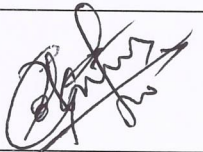
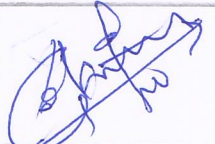
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78	Dr C. Sunanda Yadav	Head of Ph.D Department	Tilak Maharashtra Vidyapeeth	Maharashtra	9890574497	sunandayadav@yahoo.com	<i>Sunanda Yadav</i>
79	Dr. Santosh Dnyanobarao Kadam	I/C Librarian	Vasantryao Naik Marathwada Krishi Vidyapeeth, Parbhani	Maharashtra	9960317907	ksantosh016@gmail.com	
80	Dr. Prasad Gokhale	Director (Research)	Vishwakarma University	Maharashtra	9823388933	prasad.gokhale@vupune.ac.in	<i>Prasad Gokhale</i>
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84	Prakash Vijay Barve	Assistant Librarian	Yashwantrao Chavan Maharashtra Open University Nashik	MAHARASHTRA	9403774540	prakashbarve123@gmail.com	

*Prakash Vijay Barve Asst Librarian*

*PMU*

*11 4*

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*Prashant*



## MGM INSTITUTE OF HEALTH SCIENCES

(Deemed University u/s 3 of UGC Act, 1956)

**Grade 'A' Accredited by NAAC**

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Email: [research@mgmuhs.com](mailto:research@mgmuhs.com) ; Website: [www.mgmuhs.com](http://www.mgmuhs.com)

22<sup>nd</sup> August, 2019

**Sub : Report on “Making academic research effective with artificial intelligence”**

A workshop under the Research Cell of the MGMIHS was conducted on **Making academic research effective with artificial intelligence** on 22<sup>nd</sup> August, 2019 at 3<sup>rd</sup> floor, Auditorium.

Prof. Sourish Dasgupta, Founder and CEO of Rygbee Inc., Professor at DA-IICT. He did his PhD in Computer Science from University of Missouri, Kansas City, USA.

Abstract: Academic research is challenging, to say the least. There are several reasons why research becomes slow and frustrating. Much of that can be attributed to ineffective methods that researchers usually adopt, instead of following certain tried-and-tested research methodologies. One can see two extremes taken by researchers - those who would not use any modern software tools available for research management, and then those who would use a plethora of tools for every single kind of research activity that they do. Both may fall into the danger of getting lost very easily.

Prof. Sourish Dasgupta will be presenting a new genre of research management tool called RAX (<https://raxter.io>) that behaves as an artificial intelligence powered personal research assistant (RA) for academic researchers.

Total 176 nos. of Faculty and Students attended the lecture.

Faculty	:	87 Nos.
PhD Students	:	46 Nos.
MSc Students	:	43 Nos.

Feed back on the lecture was taken and is submitted.

Dr. Sabita M Ram  
Director (Research)



# RAX WORKSHOP

## Making Academic Research more effective using A.I

Introduction to RAXter.io - research productivity tool

by **Dr. Sourish Dasgupta**  
CEO, Founder RAXter.io  
Assitant Professor, DA-IICT

Boost your research output using RAX

<https://raxter.io>

- Improve discovery of resources
- Increase research productivity
- Streamline research workflow



Sourish Dasgupta  
CEO, Founder RAXter.io

**22nd August | 9:30 AM**

 **MGM Institute of Health Sciences**

visit: <https://raxter.io> to know more about the tool



Title: Making academic research effective with A.I.

Abstract: Academic research is challenging, to say the least. There are several reasons why research becomes slow and frustrating. Much of that can be attributed to ineffective methods that researchers usually adopt, instead of following certain tried-and-tested research methodologies. One can see two extremes taken by researchers - those who would not use any modern software tools available for research management, and then those who would use a plethora of tools for every single kind of research activity that they do. Both may fall into the danger of getting lost very easily. Prof. Sourish Dasgupta is going to present a new genre of research management tool called RAX (<https://raxter.io>) that behaves as an A.I. powered personal research assistant (RA) for academic researchers. Building upon his argument that existing tools such as discovery engines and reference managers are not sufficient enough for the subjective and evolving needs of researchers, Prof. Dasgupta will elucidate the key use-cases that is often ignored and which RAX addresses. Prof. Dasgupta would be very happy to entertain questions related to the A.I. behind RAX or his journey into the world of startups from the world of academia.

Short biography:

Dr. Sourish Dasgupta is a professor turned entrepreneur who wants to contribute to bringing up a lot more creative, imaginative and sharing researcher generation. He loves studying and discussing artificial intelligence, theoretical linguistics, culinary art, comparative religion, and Tintin. He is currently the Founder and CEO of Rygbee Inc., and also a professor at DA-IICT. In his pastime, Prof. Dasgupta loves to cook and debate with students. He wants to be either a monk or a hippie in his next life. Prof. Dasgupta did his Ph.D. in Computer Science from the University of Missouri - Kansas City, USA.

Handwritten signature in blue ink, possibly reading "Sourish Dasgupta".



# Artificial Intelligence Seminar

Sl. No.	NAME	SIGN	TEL. NO	DESIGNATION
	Mokshil Shah	<del>Shah</del>	6511564002	MSc Clinical Embryology
1)	Sanica Nadkarni	<del>Sanica</del>	9702286490	MSc Molecular Biology I
2)	Anand Shukla	<del>Shukla</del>	8097558113	MSc Molecular Biology I
3)	Ankit Hingode	<del>Hingode</del>	22150224118	MSc Molecular Biology
4)	Paval yash	<del>yash</del>	977330951	MSc Molecular Biology
5)	DiPai Bhoise	<del>Bhoise</del>	7350457294	MSc Molecular Biology
6)	Aaradhana sharma	<del>sharma</del>	7795696271	MSc Molecular Biology
7)	Parte Aishwarya Y.	<del>Aishwarya</del>	9702327722	MSc Biostatistics
8)	Kalpesh Vishe	<del>Vishe</del>	9823421584	MSc Molecular Biology
9)	Sonali Medekar	<del>Medekar</del>	8693039714	MSc Medical Biochemistry
10)	Minal D. Raoane	<del>Raoane</del>	9527602857	MSc Biostatistics
11)	Sneha Rokade	<del>Rokade</del>	9604544891	MSc Biotechnology II
12)	Rajni Nantyal	<del>Nantyal</del>	9634696907	MSc. Medical Biotech III
13)	Madhu Singh	<del>Singh</del>	9324732592	"
14)	S. Kalavani	<del>Kalavani</del>	9629791781	MSc. Medical Biotech III Sem
15)	Oshin Akolkar	<del>Akolkar</del>	9594601444	MDS - OMFS 1st yr.
16)	Manisha Shinde	<del>Shinde</del>	9657825387	MDS - OMFS 1st yr
17)	Sreelaxmi P. S	<del>S</del>	8879946502	NPCC 2nd yr
18)	Athira Chandan	<del>Chandan</del>	8692054049	NPCC 2nd yr
19)	Jignesh Vyas	<del>Vyas</del>	9768986498	NPCC 2nd yr
20)	Aasiya Khan	<del>Khan</del>	9833128868	MSc Biotech II
21)	Shraddha Kadve	<del>Kadve</del>	9594240934	MSc Medical Biotech II
22)	Smrithi Pimpalay	<del>Pimpalay</del>	8308359599	MSc. Medical Genetics
23)	Gauri Lambhate	<del>Lambhate</del>	7972528574	MSc Medical Genetics
24)	Tram Khalbe	<del>Khalbe</del>	8097039897	MSc. Medical Biotech
25)	Shaista Khan	<del>Khan</del>	9768449689	MSc. medical Biotech
26)	Ashitosh Shivekar	<del>Shivekar</del>	8169740292	MSc Medical Biotech



Sl. No.	Name	Phone No.	Signature	Qualification
22	TANVI SAWANT	7841803218		Rs. (MSc Med. Genet)
23	Sonali Ramakant Shivalkar	8308596970	Shivalkar	
24	Pooja Shyamshankar Singh	9689975165	Pooja	
25	Ayesha Majid Shaikh	7798554175	Aisayyad	
26	Shweta Shatrughna Shinde	9987357005	Shinde	(MSc-BTK)
27	Aamreen Ryain	9021937144		(MPT-Neuro)
28	Neena Vaughan	9833378283	Neena	(MPT-ortho)
29	Karishma Wagh	9725399070		(MPT-ortho)
30	Bhanat kupte	9029975452		(MDS-Periodont)
31	Yash Jha	9088448247	Yash	(M.S.C. M + Genet)
32	Dr. Neha Patil	9322516960	Patil	(MDS-DMDR)
33	Cleon D'souza	9930533078		(MII-MDS-Endo)
34	Dr. Shreyal Deshmukh	9619496542	Deshmukh	(II MDS-Endo)
35	Dr. Gaurav Chaudhary	9505059008	Ch	(I MDS-Endo)
36	Dr. Saloni Brandan	7304424196	Saloni	(I MDS-Endo)
37	Dr. Yashaswi Chaudhary	9208263081	Yashaswi	(MDS-I Endo)
38	Dr. Varsha Urlam	9833462595	Urlam	(IMDS-Perio)
39	Dr. Aditya Pawar	8600571955	Aditya	(IMDS-Perio)
40	Dr. Siddhesh Save	9892974489	Siddhesh	(IMDS-Ortho)
41	Dr. Jayesh Jadhav	9096518925	Jadhav	(IMDS-Ortho)
42	Dr. Saagar Mishra	9820172789	Saagar	(IMDS-Ortho)
43	Dr. Ashima Madavi	8856004811	Ashima	(IMDS-Perio)
44	Dr. Aishwarya Deshmukh	8329059459	Aishwarya	(IMDS-Prosth)
45	Dr. Anjali Chavan	9146609797	Anjali	(IMDS-Prosth)
46	Dr. Nishant Das	8390222660	Nishant	(II MDS-Prosth)
47	Dr. Ankita Savaroya	7738777692	Ankita	(II MDS-Prosth)
48	Dr. Paraksh Reddy	9881735991	Paraksh	(II MDS-Prosth)
49	Dr. Mithilesh Ukey	8888807228	Mithilesh	(II MSc-Med Genetics)
50	Dr. Vishakha Dhulekar	9137316542	Vishakha	(IMSC-Medical Genetics)
51	Dr. Smriti Patil	8898115552	Smriti	(IMSC-Medical Genetics)
52	Dr. Supriya Bhauri	9930385524	Supriya	(IMSC-Medical Genetics)
53	Dr. Madhura Pathak	8956664001	Madhura	(IMSC-Medical Biotech)
54	Dr. Divya Pragaspati	7046171060	Divya	(MSc. Genetics)
55	Dr. Raj Vashi	8347737100	Raj	(MSc. Medical Biotech)
56	Dr. Neeraja J P	9895709320	Neeraja	(MSc. Med Genetics)



28	Mrs. Susan Jacob (10)	9870518957	Phd	Professor (Nursing)
29	Dr. Samanthini Shiv	9869433662	B.S	Professor (Gen. Dental)
30	Dr. Vanitha Shewy	9167629730	Vanitha 22/8/19	Dean, HOD Conservative Dent. & Endodontics MAM DCH
31	Dr. Smruti Narayan	9769088803	Phd 22/8/19	HOD, Professor Experimental Maxillofacial Surgery MAM DCH
32	Dr. Nisha Asnani	982089718	Phd 24/08/19	Professor Dept of OMFS. MAM DCH
33	Dr. Jyoti Wadpure	9820641113	Phd	Prof. - Prosthodontics
34	Dr. Madhani Manekar (11)	9819396116		Asso. Professor Comm. med. MAM
35	Dr. Santhi Kulkarni	9867574578		Asst. Prof. MAM
36	DR. SHARVARI A. SAMANT	9820841231		Asso. Prof. Micro Prof, Micro MAM
37	Dr. Anahita Hodiwala	9820031818		
38	Sonali Banerjee (12)	9131820712		PhD Scholar Dental
39	Dr. Pradip Jadhav	9819034283		Associate Prof Pharmacology
40	Dr. Adil Ganderwala	9096815606		Asso Prof. Oral Maxillofacial Surgery
41	Dr. SUNIL SIDANA	9820798821		Professor, OMFS
42	Dr. Rita M. Khadkure	9619597074		Asso Prof. Physiology MAM
43	Dr. Swati Gaoali	9960540526		Asst. prof. physiology
44	Dr. M. V. Halkh	9619819864		Asso. prof. physiology
45	Prapti Gandhi	9167717782 (26)		M.Sc. Clinical Nutrition
46	Vaikhori Bagul	9420304509 (30)		M.Sc. Clinical Nutrition
47	Padmaji Phawale	9967752873		PhD Scholar - Nursing
48	Jyoti Maroya	7039898060		M.Sc. MRIT
49	Shreya Nityanand	8928882614		M.Sc. MRIT
50	Afrin Kawdhale	9890638382 (30)		M.Sc. Pharmacology
51	Heeral Chauhan	9921144084 (31)		M.Sc. Pharmacology



Name Making Academic Research Effective With Artificial Intelligence by Dr. Souresh Das

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2) Ms. Vandana Kumbhar	9321721222		
3) Mrs R. Ponchitra	9167694489		Vice Principal
4) Mrs Pruthi Hattis	9819279364		Associate Professor
5 Ms. Salini Sasidharan	8691893368		Tutor
6 Mrs. Ritika Gawade	7045079105		Lecturer
7. Ms. Anna Hemia Thomas	9004961439		Tutor
8. Mrs. Ferganza Subikon	7678087800		Tutor
9. Mrs. Sanjivta B. Mohanty.			Tutor
10. Mr. Jignesh Bhatt	8828184049		Msc Nursing
11. Mr. NITHIN N	9747323793		Msc Nurse
12. Mr. Siddheshwar Awatede	9011812158		
13. Ms. Divya Bhadwaj	7018038898		Msc Nursing
14. Ms. Rushma Naie	8356991918		Msc (N)
15. Mr. Vikas patidar	9004654194		Msc (N)
16. Ms. Rafiya Sangameshwar	8689857983		Msc. Clinical E
17. Ms. Sweta D. Gowda	8655178204		Msc Clinical Embryology
18. Ms. Kshamata R. Joshi	7506192305		Msc: Clinical Embryology
19. Dr. Jyoti Chaudhari	9833984291		Asso: Prof.
20. Mrs. Rupali Gujar	8652337111		PhD scholar
21. Dr. Vruchali Panhale	986769843		Principal, MGM college of Physiotherapy
22. Bela Aparnael	9819000674		Associate Prof, MGMS
23. Dr. Savita Shalaw	9819271578		Prof & Head Pharmac
24. Dr. MERUNA BOSE	9820737817		Prof & Vice Principal MGMSOP, NM
25. Sandeep Thombare	7798226748		Assistant prof.
26. Mr. Dipak N. Khadke	9970953676		Lecturer (MGM Aurangabad)
27. Mr. Pray Jimmy	9637143887		Lecturer (MGM CON Washi)



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mobile no.

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Ms. Briny Darwin	8600007132		Briny
Ms. Uzma Hamdule	9137423954		Uzma
Ms. Shivani Bhate	9407235175		Shivani
Ms. Sonal Tiwari	8652101689		Sonal
Ms. Ankita Baburav Patil	7039512874		Ankita
Ms. Apurva Patil	7304102195		Apurva
Ms. Smital K (13)	<del>7884</del> 8169435611	PhD Biotech	Shubham
Mr. Shubham	788777078	MSc. MRIT	Agarwal
Ms. Amala M George	8850479241	MSc Biotech	elvis
Ms. Elizaph Pejt	9969836813	MSc Biotech	Jaya Parika
Ms. Jaya Parika (14)	9768401102	PhD Med genetics	
Ms. Chetna Kanade	7039482684	MSc. Med Biochemistry	Kanade
Mr. Susmit Dhinde	8551966860	PG. BMed Biochemistry	Dhinde
Ms. Anagha B. Mare	8082168080	MSc-I Clinical Nutrition	Mare
Ms. Rashmi kumar sah	9702793757	MSc-III Med. Biochemistry	Rashmi
Ms. Anita .p. yadav	9765081089	MSc-II Med Biochemistry	Anita
Ms. Ilma Siddharu	8097171018	MSc II Med. Biochemistry	Siddharu
Ms. sarita yadav	8668359299	MSc II Med. biochemistry	Sarita
Mr. Aminkumar Dhule	9766939301	NPCC II <sup>nd</sup> year.	Amin
Ms. Precious. Angel Josey	8291342193	NPCC II <sup>nd</sup> year	Precious
Ms. Perce's Gracy	8839221075	Msc II <sup>nd</sup> year	Gracy
Ms. Anusha John	9930624609	NPCC II YEAR	Anusha
Ms. R. Kavitha	8108104705	MSc(N) -II Yr.	Kavitha







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Smriti  
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Dr Ishita Jain

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Ishita

Aditi erendi

Dr. Akash Hegdekar

43  
44  
45

2 MSc Biosci  
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Dr. Manasi Kale

Sarvesh Jadhav

39

Manasi

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Tarun P

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**MAHATMA GANDHI MISSION  
MEDICAL COLLEGE & HOSPITAL, NAVI MUMBAI**

Junction of NH-4 & Sion Panvel Expressway Sector -1, Kamothe, Navi Mumbai -410 209.

Tel no – 022/27433404, 27437904

**MEDICAL EDUCATION UNIT**

**Workshop for Teaching Faculties on “Writing Research Projects”**

Dates: 14<sup>th</sup> to 16<sup>th</sup> October 2020 Time: 10 am to 1.00 pm Venue: 3<sup>rd</sup> floor Auditorium, MGM Med College Building

Resource Faculty: Dr. Bani. B. Ganguly, Honorary Professor cum Research Advisor, MGMIHS, Navi-Mumbai.

Sr. No.	Name	Dept	Designation	Email id	Mobile No	Signature of participants		
						Dates	14/10/2020	15/10/2020
1	Dr. Rita M. Khadkikar	Physiology	Associate Professor	ritumk@gmail.com	9619597074			
2	Dr. Yashoda R. Kattimani	Physiology	Associate Professor	yashoda.ravindra@yahoo.com	9969042925			
3	Dr. Sameer Kadam	General Surgery	Professor & Head	dr.sameerkadam@gmail.com	9594773336			
4	Dr. Mukesh Soni	General Surgery	Assistant Professor	mic19june@gmail.com	+91 8742902889			



Sr. No.	Name	Dept	Designation	Email id	Mobile No	Signature of participants		
						14/10/2020	15/10/2020	16/10/2020
5	Dr. Amrit Kejriwal	General Medicine	Professor	amritkejriwal@rediffmail.com	9892691603			
6	Dr. Babita Ghodke	General Medicine	Associate Professor	ghodke.babita@gmail.com	9321262132			
7	Dr. Priti Srivastava Kapoor	Radiology	Professor & HOD	dr.pritikaps@gmail.com	8850148850			
8	Dr. Prasad Waingankar	Community Medicine	Professor & Head,	hodpsmmgmmcm@gmail.com	9324714313			
9	Dr. Nisha Relwani	Community Medicine	Associate Professor	relwani_nisha@yahoo.com	9545455853			
10	Dr Vijay Kamale	Paediatrics	Professor & HOD	drvijaykamale@yahoo.co.in	9224475712			
11	Dr Suhas Kharche	Paediatrics	Assistant Professor	drsuhaskharche@rediffmail.com	9823446339 9623446339			
12	Dr. Vishwas Sathe	Anaesthesiology	Professor	vishwasathe@gmail.com	9769 981 999			
13	Dr Deepika Sathe	Anaesthesiology	Associate Professor	sareendeepika31@gmail.com	9819 869 990			

14	Dr. Mrunal Pimparkar	MEU Co-ordinator & Professor, Community Medicine	MEU Co-ordinator & Professor, Community Medicine	drseema23@gmail.com	9821661558	 14/10/2020	 15/10/2020	 16/10/2020
15	Dr. Z. G. Badade	Biochemistry	Professor	badadezg@gmail.com	9322880252	 14.10.20	 15.10.20	 16.10.20
16	Dr. Kavita More	Biochemistry	Associate Professor	kavitatmore@gmail.com	9224484406	 14.10.20	 15.10.20	 16.10.20
17	Dr. Anjali Sabnis	Anatomy	Professor & HOD	dranjus2003@yahoo.com	9820493036	 15-10-2020	 15-10-2020	 16-10-2020
18	Dr. Charushila Shinde	Anatomy	Associate Professor	charushila29@gmail.com	9420112269	 14.10.2020	 15.10.2020	 16.10.2020
19	Dr Samir Pachpute	Microbiology	Associate Professor	drsamirpachpute@gmail.com	9594937755	 14/10/2020	 15/10/20	 16/10/2020
20	Dr. Savitri Katlam	Pharmacology	Assistant Professor	savitrikatlam@gmail.com	9867514578	 14/10/20	 15/10/20	 16/10/20
21	Dr. Deepanjana Dass	Pharmacology	Assistant Professor	ddass1985@gmail.com	9930361068	 14/10/20	 15/10/20	 16/10/20
22	Dr. Sonia Nikita Misquitta	Radio diagnosis and Imaging	Assistant Professor	sonnikita@gmail.com	9167499459	 14/10/20	 15/10/20	 16/10/20
23	Dr. Shaifali Patil	OBGY	Associate Professor	patilshaifali@gmail.com	8779550588 9820333463	 14/10/20	 15/10/20	 16/10/20









**MAHATMA GANDHI MISSION MEDICAL COLLEGE & HOSPITAL ,  
AURANGABAD**

**Academic Event Report**

Conferences/ Seminars/ CME/Workshop/ Quiz/ Debate/ Guest Lecture etc.

Date:- 11-08-2019

No.	Event Report
1.	Name & Level of Event – College/ Regional/ State/ National/ International.  Site Initiation Visit , –Workshop, National level.
2.	Background/ Introduction – Need/ reasons for holding the prg, Name of Association/ Collaboration etc. Survey to collect voice samples of patients and age matched healthy individuals.
3.	Venue -  • Pharmacology Department, MGM Medical College Aurangabad
4.	Sponsors – Name & details If any  Sonde /Quest CRO.
5.	Inauguration – including the details of Chief Guest, Guest(s) of Honor, gist of speeches given, compared by etc.....  • CHIEF GUEST: - Dr. Deepak Bhosle, Dr. Jyoti Bobde Compared: - Dr. Deepak Bhosle.
6.	Speakers/ Judges/ Chairman/ Panel Team – Brief introduction with their achievements.  Speakers : • Dr. Deepak Bhosle (HOD Pharmacology, MGM Medical College, Aurangabad) • Dr. Prasad Jadhav
7.	Participants & Delegates – No of participants & delegates/ teams with their names.  All Study staff
8.	Prize Distribution etc – Brief Summary of the Proceeding





**MAHATMA GANDHI MISSION MEDICAL COLLEGE & HOSPITAL ,  
AURANGABAD**

**Academic Event Report**

Conferences/ Seminars/ CME/Workshop/ Quiz/ Debate/ Guest Lecture etc.

9.

**Valedictory Ceremony** – *Brief of the proceedings including chief guest etc and who conducted it.*

10.

**Highlights of the Event** – *Brief about the main highlight(s) of the event.*

- Site Staff, Facilities and Study Supplies
- Compliance to Protocol/Amendment(s) and regulatory requirements
- Subject Recruitment & Enrollment
- Informed Consent Procedures/Process
- Case Report Form (CRF) / Electronic Case Report Form (eCRF) Requirements
- Data Entry and Query Resolution Timelines
- Monitoring Procedures
- IP storage and accountability
- Laboratory Procedures and Biological Samples
- Essential Documents and ISF review

**Professor & Head  
Pharmacology Department  
MGM Medical College & Hospital, Aurangabad**





**MAHATMA GANDHI MISSION MEDICAL COLLEGE & HOSPITAL ,  
AURANGABAD**

**Academic Event Report**

Conferences/ Seminars/ CME/Workshop/ Quiz/ Debate/ Guest Lecture etc.

Date:- 03-sep-2019

No.	Event Report
1.	<b>Name &amp; Level of Event – College/ Regional/ State/ National/ International.</b>
	<b>Site Initiation Visit , –Workshop, National level.</b>
2.	<b>Background/ Introduction – Need/ reasons for holding the prg, Name of Association/ Collaboration etc.</b>
	“A Multicentric, Randomized, Open Label Clinical Trial to Evaluate Efficacy and Safety of Tapentadol Nasal Spray in Comparison to Tramadol Immediate Release Capsule and Intravenous Injection in Patients with Post-Operative Moderate to Severe Pain. ”
3.	<b>Venue -</b>
	<ul style="list-style-type: none"><li>• Pharmacology Department , MGM Medical college AURANGABAD</li></ul>
4.	<b>Sponsors – SIRO</b>
	<b>SIRO CRO</b>
5.	<b>Inauguration – including the details of Chief Guest, Guest(s) of Honor, gist of speeches given, compared by etc.....</b>
	<ul style="list-style-type: none"><li>• CHIEF GUEST: - Dr. Tejindersingh Chhabda, Dr. Amey Chakkarwad</li><li>Compared: - Dr. Deepak Bhosle.</li></ul>
6.	<b>Speakers/ Judges/ Chairman/ Panel Team – Brief introduction with their achievements.</b>
	<b>Speakers :</b> <ul style="list-style-type: none"><li>• Jasmita Kaur (Clinical Research Associate, SIRO)</li></ul>
7.	<b>Participants &amp; Delegates – No of participants &amp; delegates/ teams with their names.</b>
	<b>All Study staff</b>
8.	<b>Prize Distribution etc – Brief Summary of the Proceeding</b>





**MAHATMA GANDHI MISSION MEDICAL COLLEGE & HOSPITAL ,  
AURANGABAD**

**Academic Event Report**

Conferences/ Seminars/ CME/Workshop/ Quiz/ Debate/ Guest Lecture etc.

**9.** **Valedictory Ceremony** – *Brief of the proceedings including chief guest etc and who conducted it.*

**10.** **Highlights of the Event** – *Brief about the main highlight(s) of the event.*

- Site Staff, Facilities and Study Supplies
- Compliance to Protocol/Amendment(s) and regulatory requirements
- Subject Recruitment & Enrollment
- Informed Consent Procedures/Process
- Case Report Form (CRF) / Electronic Case Report Form (eCRF) Requirements
- Data Entry and Query Resolution Timelines
- Monitoring Procedures
- IP storage and accountability
- Laboratory Procedures and Biological Samples
- Essential Documents and ISF review

**Professor & Head**

**Pharmacology Department**

**MGM Medical College & Hospital, Aurangabad**



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<b>Site No.</b>	21	<b>Date of Visit</b>	03-Sep-2019
<b>Date of Last Visit</b>		<b>Visit No.</b>	SIV

## Site Details

<b>Principal Investigator</b>	Chhabda Tejinder Singh
<b>Institution Name</b>	MGM Medical College & Hospital
<b>Primary Address</b>	MGM Medical College & Hospital Address: N-6, Cidco, Aurangabad, Maharashtra 431003 Phone: 0240 660 1100 Aurangabad Maharashtra India 431003

## Site Staff Present

Name	Role	Visit Date
Shaikh Ayesha	Site Coordinator	03-Sep-2019
Shaikh Yahiya	Site Coordinator	03-Sep-2019
Bhale Pramod	Co-ordinating Investigator	03-Sep-2019
Chudavekar Mahesh	Site Coordinator	03-Sep-2019
Ansari Ashfaque	Sub Investigator	03-Sep-2019
Chhabada Tejinder Singh	PI	03-Sep-2019
Chakkarwar Amey	Co-ordinating Investigator	03-Sep-2019
Rajput Yuvraj	Co-ordinating Investigator	03-Sep-2019
Thakur Lindpadmaja	Site Coordinator	03-Sep-2019

## Non Site Staff Present

Name	Role	Visit Date
Oza Jasmita	CRA	03-Sep-2019

## Site Visit Summary

None

## New and Outstanding Action Items

21-000003	
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## New and Outstanding Action Items

Issue No.		Description
<b>Date Identified</b>	16-Sep-2019	EDC Access for PI is yet to be created
<b>Date of Completion</b>		
<b>Status</b>	Open	<b>Corrective and/or Preventive Action</b>
<b>Protocol Deviation</b>	No	
<b>Issue No.</b>	21-000006	<b>Description</b>
<b>Date Identified</b>	18-Sep-2019	EDC Account for PI-Dr Tejinder Chhabada is yet to created
<b>Date of Completion</b>		
<b>Status</b>	Open	<b>Corrective and/or Preventive Action</b>
<b>Protocol Deviation</b>	No	
<b>Issue No.</b>	21-000005	<b>Description</b>
<b>Date Identified</b>	16-Sep-2019	Updated IU including Dr. Asfaque Ansari as a ENT specialist needs to be collected .
<b>Date of Completion</b>		
<b>Status</b>	Open	<b>Corrective and/or Preventive Action</b>
<b>Protocol Deviation</b>	No	

## Documents Collected

Document	Collected	Comments
No records available.		

## 1 INVESTIGATOR'S RESPONSIBILITY

Evaluation	Response
<b>Have the following items been discussed as per ICH GCP/ regulations/ sponsor requirements?</b>	
<b>a. Investigator and site staff responsibilities</b>	<b>Yes</b>
<b>Comments :</b>	



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## 1 INVESTIGATOR'S RESPONSIBILITY

<b>Evaluation</b>	<b>Response</b>
<p>GCP training as per "GCP and Investigator Responsibilities" slides was discussed with site team. Training provided to all site members listed in the delegation log :- Dr Tejinder Chhabada :-PI Dr Yuvraj Rajput :-Co-PI Dr Pramod Bhale :Co-PI . Dr. Amay Chakkarwar :-Co-PI Dr. Ashfaque Ansari :-ENT Nasal Examination Linpadmaja Thakur :CRC 1 Yahiya Shaikh:CRC 2 Mahesh Chudavekar :-CRC3 Ayesha Shaikh:-CRC 4 Kalyani Akolkar :-Study Nurse 1 Satyasheela Kamble :-Study Nurse 2</p>	
<b>b. Requirement for protocol adherence</b>	<b>Yes</b>
<p><b>Comments :</b> protocol ver 2.1 dated 21 Dec 2018 was discussed along with the IB for Tapentadol Vers 5 dated 01 Mar 18 sponsor has provided memo to protocol dated 6 Aug 19 has been explained to site and site was asked to notify the same to EC. PI had following query PI:-Can Up titration of doses be allowed during treatment . CRA:- No , uptitration of doses will not be allowed during the study . However, frequency of study drug can be adjusted on 24th, 48th, 72nd and 96th hr accordingly . Rescue medication can be given as permitted by protocol . PI :-C-sections can be included in the study ? CRA:-No , as Pregnancy and lactation are exclusion criteria. PI:-Are analgesic be allowed prior to the randomisation. CRA:-Yes, Analgesic will be allowed prior and during the surgery and not allowed post surgery .</p>	
<b>c. Medical care of trial subject</b>	<b>Yes</b>
<p><b>Comments :</b> PI was informed this being a phase III study, he would be expected to continue medical care of the subject as per routine practise, keeping in mind the protocol requirements of visits and assessment</p>	
<b>d. Delegation of study tasks; delegation to qualified staff</b>	<b>Yes</b>
<p><b>Comments :</b> PI and site staff were informed about correct delegation of staff to various activities pertaining to the trial as per ICH GCP principles, during this visit. Delegation log was completed by PI and the site team were delegated to activities as per their training, education and experience.</p>	
<b>e. Time allocation to the study by the study staff</b>	<b>Yes</b>
<p><b>Comments :</b> Recruitment period of 01 month was informed to site and approx 4 -05 subjects per week needs to be enrolled</p>	
<b>f. Need to prevent unauthorized access to study documentation, confidential study information and study supplies,</b>	<b>Yes</b>





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<b>1 INVESTIGATOR'S RESPONSIBILITY</b>	
<b>Evaluation</b>	<b>Response</b>
<b>including the investigational product</b>	
<b>Comments :</b> PI and his team was informed that the source documents (Original/ attested Photocopies) and study material shall be maintained under secured access in cup boards at clinical research room . Documents will only be accessed by the research team. Apart from Source documents, IP must be too in the secured area. The access to IP and source documents must be restricted.	
<b>g. Requirements for day-to-day storage and archival of documents</b>	<b>Yes</b>
<b>Comments :</b> All the study related documents will be stored in the cupboards. Site was requested to store all the documents in one cupboard and to label it. The study coordinator was asked to ensure that all study documents are placed in cupboards before they leave for the day.	
<b>2 PROTOCOL &amp; AMENDMENT(S)</b>	
<b>Evaluation</b>	<b>Response</b>
<b>Have the following topics been discussed?</b>	
<b>Please provide the details of Final Version of the Protocol and Protocol Amendments (If any) that were discussed</b>	<b>Yes</b>
<b>Comments :</b> Protocol version 2.1 dated 21 Dec 2018 was discussed during the visit. No concern was raised from PI or his team.	
<b>a. Rationale</b>	<b>Yes</b>
<b>Comments :</b> Study rationale was discussed with the team and site team do not have any question pertaining to rationale	
<b>b. Inclusion/ exclusion criteria/ withdrawal criteria</b>	<b>Yes</b>
<b>Comments :</b> Eligibility criteria and discontinuation criteria were discussed with the study team during the visit. It was informed that screening and randomization check list along with signed and dated ECG, Lab reports , Urine reports and nasal examination has to be shared with CRA and SIRO medical team for review receptively after the screening and before randomization of the subject.	
<b>c. Study flow/ procedures</b>	<b>Yes</b>
<b>Comments :</b> The study flow and procedures were discussed and explained to the site staff. Laminates and source notes were used for the training the site staff.	
<b>d. Investigational product handling</b>	<b>Yes</b>
<b>Comments :</b> IP was received by the site on 07-Sep-2019, all details of IP handling along with temperature log and instruction to use the thermos hygrometer were shared with site. Primary CRA, Mr Prashant has mail confirmation for drug being fit for use and transit temperature log along with shipment document in the ISF. Site was also informed that each kit would contain the following and the storage condition. Tapentadol: 2 Nasal sprays -Storage conditions 20- 25 °C in Upright condition, excursion permitted between 15 °C to 30 °C	



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<b>2 PROTOCOL &amp; AMENDMENT(S)</b>	
<b>Evaluation</b>	<b>Response</b>
<p>Tramadol: 12 ampules and 6 strips containing 10 capsules/ strip.            Storage conditions Tramadol ampoules: store under 25 °C, dry place.            Storage conditions Tramadol capsules: store under 25 °C, dry place, protect from light.</p> <p>IP will be Stored at controlled access cupboards.</p> <p>Site was informed each subject would be dispensed 1 kit as per randomization schedule and the medication would be dispensed on daily basis as per dose and frequency. The IP kit is to be maintained under protocol specified conditions at all times even when dispensed to the subject and treatment is ongoing.</p>	
<b>e. Efficacy and safety end points/ parameters</b>	<b>Yes</b>
<p><b>Comments :</b>            Primary and secondary efficacy endpoints and safety monitoring parameters were discussed with site and importance of accurate administration of patient reported outcome was emphasised during the discussion.</p>	
<b>f. Study specific evaluations</b>	<b>Yes</b>
<p><b>Comments :</b>            Protocol was discussed w.r.t schedule of events. Site was informed about the lab parameters, ECG and other procedure timepoints. Laminates were shared to explain the flow of activities per protocol.</p>	
<b>g. Concomitant medications</b>	<b>Yes</b>
<p><b>Comments :</b>            Protocol was discussed w.r.t permitted and prohibited medications. Site team was informed all the pre, during and post-surgery medications would have to be entered in EDC.</p>	
<b>h. Study completion/ early patient withdrawal/ study timelines</b>	<b>Yes</b>
<p><b>Comments :</b>            It was informed that though the study treatment duration was for 5 days, subject could be discharged after 72 hrs if the pain score was 0.</p>	
<b>i. Study logistics</b>	<b>Yes</b>
<p><b>Comments :</b>            SIV kit consisting Site file (03), Source notes , Eligibility checklist , Patient file, Thermohgrometer , EDC access Form was provided to the site . Site was provided with the contact details of CTA for any need of any logistics.</p>	
<b>j. The process of protocol amendment(s) and responsibilities of investigator site in relation to protocol amendment(s)</b>	<b>Yes</b>
<p><b>Comments :</b>            The site was trained on the process to be followed in case of amendment to the study protocol including EC submission and Approval, DCGI approval.. etc</p>	
<b>k. Protocol deviations and violations, its documentation and notification process</b>	<b>Yes</b>
<p><b>Comments :</b>            The site was informed about the process of reporting Protocol Deviations (PD) and violations. The site has been informed to notify any observed PD's or Protocol Violations to the EC and to obtain acknowledged copy. Possible PDs were also discussed with the site.</p>	





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<b>3 RECRUITMENT AND STRATEGIES</b>	
<b>Evaluation</b>	<b>Response</b>
<b>Items discussed</b>	
<b>a. Recruitment (number, timelines) and global status (if applicable)</b>	<b>Yes</b>
<b>Comments :</b> The CRA informed the site about the recruitment target of 10 patients per week . Recruitment period of 01 month was informed to site. PI and his team were informed that per the current recruitment timelines, site needs to screen patient till end of Sep. PI was told that incase of any extension in the recruitment period, CRA will revert immediately.	
<b>b. Strategies for recruitment: advertisements, camps, referrals etc.</b>	<b>Yes</b>
<b>Comments :</b> The site team has confirmed that they will be able to get the patient form the OPD. PI will not refer patients from other source.	
<b>4 INFORMED CONSENT PROCEDURE</b>	
<b>Evaluation</b>	<b>Response</b>
<b>Items discussed</b>	
<b>a. The procedure for obtaining &amp; documenting consent (where applicable Audio Video Consent)</b>	<b>Yes</b>
<b>Comments :</b> None	
<b>b. Need to use the current IRB/IEC approved version/ translations</b>	<b>Yes</b>
<b>Comments :</b> it was informed to the site to use the EC approved version to obtain informed consent form (ICF) as per the EC approval letter. In case of revision to the approved ICF's, site was advised to use it for consenting post EC Approval. In the meantime, updated safety information if any, must be shared with the ongoing subjects at the earliest possible. Site was advised to document this is the subjects source notes. Currently aproved and implemented ICFs are mentioned below English:Master Version 2.1 dated 21 Dec 2018 Marathi: Reference: Version: India – Marathi – Version 2.1 dated 16 Jan 2019; Reference: English- Master Version 2.1 dated 21 Dec 2018 Hindi:Version: India – Hindi – Version 2.1 dated 10 Jan 2019; Reference: English- Master Version 2.1 dated 21 Dec 2018	
<b>c. Scenarios for using legally acceptable representative/ and/or impartial witness</b>	<b>Yes</b>
<b>Comments :</b> The site was informed about the following: - I. Illiterate patient: Thumb impression of the patients must be obtained on the ICF in the presence of the Impartial witness. Impartial witness must be present during the consent administration process incase patient is unable to read the consent document. ii. All necessary information about subject and impartial witness must be collected by the site in compliance with local requirements. (including identity proof of the IW) iii. IW has to be impartial to the site and its team members. Hence Subject's relative could act as IW	
<b>d. Need to inform serious GCP violations related to informed consent to the IRB/IEC</b>	<b>Yes</b>



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## 4 INFORMED CONSENT PROCEDURE

Evaluation	Response
<b>Comments :</b> Importance of notifying GCP violations to the EC was shared with the site. Site was explained about the important of the ICF process. Site was told that any violation in the consent process will be considered as serious GCP violation and each violation must be notified to EC immediately.	
<b>e. The site's responsibility to provide a copy of the subject information &amp; signed informed consent form including insurance obligations to the subject in the language best understood (read and write) by the subject.</b>	<b>Yes</b>
<b>Comments :</b> Prior to consenting, site was advised to confirm the language best understood by the patient and/or the LAR and document the same in source	
<b>f. The site's responsibility for documentation of the subject's/ patient's written consent prior to the performance of any protocol procedures</b>	<b>Yes</b>
<b>Comments :</b> ICH GCP requirement of obtaining consent prior to performing any study specific procedure/ activity was emphasised	

## 5 SAFETY REPORTING

Evaluation	Response
<b>Have the following topics been discussed?</b>	
<b>a. Definition, reporting methods and timelines for adverse events (AEs)</b>	<b>Yes</b>
<b>Comments :</b> None	
<b>b. Definition, reporting methods and timelines for serious AEs (SAEs)</b>	<b>Yes</b>
<b>Comments :</b> None	
<b>c. Requirements for follow up of subjects</b>	<b>Yes</b>
<b>Comments :</b> None	
<b>d. Withdrawal of subjects as an investigator decision</b>	<b>Yes</b>
<b>Comments :</b> None	
<b>e. Procedures for reimbursement of medical management and compensation discussed for AEs and SAEs respectively? (if applicable)</b>	<b>Yes</b>
<b>Comments :</b> None	

## 6 INVESTIGATIONAL PRODUCT (IP) / NON\_DRUG MATERIAL

Evaluation	Response
<b>Have the following topics been discussed?</b>	
<b>a. Investigator's Brochure/ summary of experience with IP including safety profile of IP or package insert</b>	<b>Yes</b>
<b>Comments :</b>	





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<b>6 INVESTIGATIONAL PRODUCT (IP) / NON_DRUG MATERIAL</b>	
<b>Evaluation</b>	<b>Response</b>
IB Ver 5 dated 1 Mar 2018 was discussed during this SIV .	
<b>b. Need for controlled access to the IP</b>	<b>Yes</b>
<b>Comments :</b> Site was reminded to maintain IP in secured location at all times. All used and unused medication must be accounted as per the IP accountability log. also Form 6 and 7 to be maintained for all the IP stocked at site	
<b>c. IP process at site, including shipping to and receipt at site, storage, handling, re-ordering, return and destruction</b>	<b>Yes</b>
<b>Comments :</b> site was trained that: 1] CRA to be informed of IP stock at site on weekly basis to allow for re-ordering of IP if required 2] shipment form and form 6 sent with each consignment to be acknowledged by site and shared with CRA real time. 3] CRA would share the transit temperature logs which are to be filed along with the shipment forms in the ISF. 4] No IP to be destroyed unless approved by Siro and Sponsor\ 5)Site was also informed to store IP below 25 degrees and at upright position .	
<b>d. IP handling on patient level, including dispensing to and return from subject, handling of unused medication and empty medication containers</b>	<b>Yes</b>
<b>Comments :</b> Site was trained each subject would be assigned a kit which would contain IP sufficient for complete treatment and back-up in case of exigencies. IP assigned to a patient should be promptly labelled with subject No and date of Randomization. only trained nurse/ delegated team to handle IP administration at assigned time and IP to be maintained at controlled temp at all times	
<b>e. Need for appropriate temperature conditions and temperature control, including action items in case of deviations (e.g. contact monitor, quarantine).</b>	<b>Yes</b>
<b>Comments :</b> None	
<b>f. Accountability procedures and documentation; criticality of 100% accountability of all IP, including discussion on relevant logs and forms</b>	<b>Yes</b>
<b>Comments :</b> Importance of 100 % accountability of the IP was discussed with the site. Site agreed to follow the same. Site was explained about the IP logs and forms required for the accountability of the IP. Site agreed to do follow all the protocol requirements.	
<b>g. The importance and process for return of expired IP</b>	<b>Yes</b>
<b>Comments :</b> The site was reminded to ensure that the expiry date is checked prior to dispensing of the study medication. Site was told to keep the expired IP kits separately and inform CRA immediately. Post CRA approval, the expired IP must be quarantined. The destruction/ return of the IP will be done post sponsor's approval. CRA must be notified immediately incase of IP misplaced.	
<b>h. Handling of NON DRUG MATERIAL (including shipment, accountability, return and documentation)</b>	<b>Yes</b>
<b>Comments :</b>	



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## 6 INVESTIGATIONAL PRODUCT (IP) / NON\_DRUG MATERIAL

Evaluation	Response
------------	----------

site was advised to maintain accountability of non drug materials like ICF, Patient materials like questionnaires. All records must be maintained right from shipment request to receipt and acknowledgement. Site was informed that incase of requirement any material, they must contact CRA immediately.

## 7 RANDOMIZATION PROCEDURE

Evaluation	Response
------------	----------

**Have the following topics been discussed?**

<b>a. Randomization procedure for the study (e.g., IVRS or manual etc.)</b>	<b>Yes</b>
---	------------

**Comments :**

Site was informed that it is Open label study. Patients will be randomized as per randomization schedule . Site Specific randomisation chart was explained to the team

<b>b. Emphasized that the randomization sequence must be followed strictly</b>	<b>Yes</b>
--	------------

**Comments :** None

## 8 CASE REPORT FORM

Evaluation	Response
------------	----------

**Have the following topics been discussed?**

<b>a. Procedures for Completion and correction conventions of CRFs as per CRF completion guidelines (CCG)</b>	<b>Yes</b>
---	------------

**Comments :**

Site was trained on the eCRF and reminded to refer to the CCG while capturing data in the eCRF. Site was informed that eCRF completion timeline of 05 days within the actual visit . The reference range for all lab parameters was shared with EDC team.

Site was informed about the importance of timely entry of the data. Site was explained that each term in the AE page is important and must be filled with the complete and proper medical terminology as it is used for the medical coding. Site was emphasized about the reference range values and the units to be entered in the RDC. Site agreed for the same.

<b>b. Expected CRF completion timeline(s)</b>	<b>Yes</b>
---	------------

**Comments :**

Site was advised to capture data in eCRF within 2-3 days upon completion of source notes. CRA shall follow up with the site for CRF completion on regular basis.

<b>c. The data query process that will be used for the study with detailed discussion on following:</b>	<b>Yes</b>
---	------------

- What will generate a query?
- How are the queries sent out?
- What should the site do with the query?
- What is the expected response time from the site?
- What happens once the site returns the query?
- What is required from the site to close the query?





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## 8 CASE REPORT FORM

Evaluation	Response
<b>Comments :</b> Basically, three types of queries shall be generated by the eCRF, Auto query, CRA query and DM query. Query raised by CRA/ DM shall have to be answered within 02 working days. Auto query are self-resolved on correction of data while query raised by CRA and DM can be closed by respective person who has raised the query. Once the response provided are satisfactory, the query raised shall be closed by the respective member	
<b>d. Importance of data being accurate and complete prior to monitor's visit.</b>	<b>Yes</b>
<b>Comments :</b> Importance of capturing data in eCRF prior to monitoring visit was advised	
<b>e. Completion and correction conventions for special tools, diaries, etc., that are created for the study.</b>	<b>Yes</b>
<b>Comments :</b> Site was reminded to make subject correct entries in questionnaires along with sign and date. Similarly all changes in source should be accompanied with attestation and only then data in EDC to be changed	

## 9 MONITORING

Evaluation	Response
<b>Have the following topics been discussed?</b>	
<b>a. Purpose, frequency and duration of monitoring visits</b>	<b>Yes</b>
<b>Comments :</b> Monitoring shall be performed to confirm that the study is being conducted in accordance with ICH GCP. Post confirmation of completion of data entry in eCRF, a site visit shall be planned within 10 days of FPI. Subsequent visits will be after every 3-4 weeks depending on enrollment at site. These timelines may change subject to the number of patients at the site and the data at the site.	
<b>b. Need for direct access to source documents, study facilities and personnel</b>	<b>Yes</b>
<b>Comments :</b> Site was advised to ensure appropriate Source documents(SD) IPD files (and its attested copy) and study documents are made available to the monitor during the monitoring visit along with delegated site staff as required. Tour of facility may also be required to reconfirm the storage of IP, Study files.	
<b>c. Availability of source documents and all study records for monitoring</b>	<b>Yes</b>
<b>Comments :</b> Site was advised to ensure appropriate Source documents(SD)including ICF and its process documentation, Medical History , Admission notes, surgery notes from surgeon, anaesthesiologist and nurses IPD files (and its attested copy) are made available to the monitor during the monitoring visit along with delegated site staff as required.  Site was also reminded not to duplicate data if already present in Doctor/ nurse's notes/ IPD notes.	
<b>d. Availability of site staff to assist with CRF review and queries</b>	<b>Yes</b>



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<b>9 MONITORING</b>	
<b>Evaluation</b>	<b>Response</b>
<b>Comments :</b> None	
<b>10 SOURCE DOCUMENTATION</b>	
<b>Evaluation</b>	<b>Response</b>
<b>Have the following topics been discussed?</b>	
<b>a. Source document is the first place where an activity is recorded.</b>	<b>Yes</b>
<b>Comments :</b> Importance of maintaining all source documents wherein the first entry was captured was discussed with the site. In case the site is unable to maintain originals in patient files, site was advised to maintain attested photocopies and make the original available for CRA's review at least one during the monitoring visit. All IPD notes, surgery notes from surgeon, anaesthetist and nurses to be made available for CRA's review. site was also reminded not to duplicate data if already present in Doctor/ nurse's notes/ IPD notes.	
<b>b. Site method of source documentation and the need for consistency across all subjects on study.</b>	<b>Yes</b>
<b>Comments :</b> Site's method of source documentation was discussed. source worksheet was share din case site wished to use the same for the study after EC notification.	
<b>c. The need for data in source and CRF to be consistent; any discrepancies must be clarified.</b>	<b>Yes</b>
<b>Comments :</b> Site was advised to capture patient data in the eCRF as is, any discrepancies noted must be clarified with appropriate comments	
<b>d. Special data collection tools/sheets (SDV worksheet) if used to record source data.</b>	<b>Yes</b>
<b>Comments :</b> None	
<b>e. Examples of source documents shared: which can include but are not limited to the following: hospital/ clinic charts, informed consent documents, laboratory requisition forms, laboratory reports and other records at the laboratory, diagnostic test (MRI, X-ray, ECG scans) and reports, subject diaries, medical history questionnaires or case histories, protocol- specific worksheets, drug dispensing/pharmacy logs, telephone logs, subject letters to the investigator, recorded data from automated instruments, microfiches, photographic negatives, microfilm or magnetic media etc.</b>	<b>Yes</b>
<b>Comments :</b> None	
<b>f. Need to certify / attest any photocopies of source data</b>	<b>Yes</b>
<b>Comments :</b> Site team was advised to attest all photocopies by the PI/ delegated personnel post review against the originals	
<b>g. Process and requirements of source data verification, necessity of access to source data by study monitor</b>	<b>Yes</b>
<b>Comments :</b> The site was advised to maintain all originals and attested photocopies for CRA's review. Originals of the	





# SITE INITIATION REPORT

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<b>Protocol No.</b>	Torrent/ Tapentadol	<b>Sponsor Name</b>	Torrent Pharmaceuticals
<b>Site No.</b>	21	<b>Date of Visit</b>	03-Sep-2019
<b>Date of Last Visit</b>		<b>Visit No.</b>	SIV

## 10 SOURCE DOCUMENTATION

Evaluation	Response
photocopies shall have top be provided to the CRA atleast once during the study for review	

## 11 ELECTRONIC SOURCE DATA/ DOCUMENTS

Evaluation	Response
<b>a. Whether site has capability of capturing source data electronically?</b>	<b>No</b>
Comments : None	
<b>b. Will these electronic documents be available for monitoring in case source data is captured electronically? (Please mention whether CRA will be provided access to sites system with CRA specific credentials or site is willing to maintain printed true copy of the source data and is willing to allow spot checks by monitor as per monitoring plan)</b>	<b>NA</b>
Comments : None	
<b>c. Is a documented process established at the site describing the following:</b> <ul style="list-style-type: none"> <li>• Regular back-up of data on the system</li> <li>• Back-up media storage in a secure location (preferably away from the investigator site)</li> <li>• Contingency plan (e.g., paper record) in case system becomes unavailable</li> <li>• Accessible data during archive period</li> <li>• Access restricted to authorized individuals?</li> </ul>	<b>NA</b>
Comments : None	
<b>d. Does a full audit trail exist (including what was entered, who entered it, when it was entered and, if appropriate, why it was changed)?</b>	<b>NA</b>
Comments : None	
<b>e. Is the system compliant to 21 CFR part 11 or Sponsor requirements?</b>	<b>NA</b>
Comments : None	
<b>f. If required, Can the electronic source be printed?</b>	<b>NA</b>
Comments : None	

## 12 ELECTRONIC DATA CAPTURE (if applicable)

Evaluation	Response
<b>a. Is there a computer available at site that will be used for the study?</b>	<b>Yes</b>
Comments : None	
<b>b. Is the internet access suitable for direct data entry (access control, confidentiality etc.)?</b>	<b>Yes</b>
Comments : EDC access for the CRC-Lindpadmaja Thakur has been generated	



# SITE INITIATION REPORT

ASD-CO-0021	Version: 06	Effective Date: 20 August 2019	Page 13 of 17
<b>Protocol No.</b>	Torrent/ Tapentadol	<b>Sponsor Name</b>	Torrent Pharmaceuticals
<b>Site No.</b>	21	<b>Date of Visit</b>	03-Sep-2019
<b>Date of Last Visit</b>		<b>Visit No.</b>	SIV

## 12 ELECTRONIC DATA CAPTURE (if applicable)

Evaluation	Response
<b>c. Is there IT/Computer support staff available at the site? If yes, &lt;provide name&gt;</b>	<b>Yes</b>
<b>Comments :</b> None	
<b>d. Is the site staff trained on EDC procedure, password policies and helpdesk for EDC?</b>	<b>Yes</b>
<b>Comments :</b> None	
<b>e. All study data have to be maintained in the site even after study completion.</b>	<b>Yes</b>
<b>Comments :</b> None	
<b>f. Were EDC accounts for Investigator and delegated site personnel activated?</b>	<b>Yes</b>
<b>Comments :</b> EDC account has been activated for CRC- Linpadmaja Thakur has been created on 23-Aug-2019. PI EDC account yet to be created. Issue raised for the same	

## 13 LABORATORY AND PHARMACOKINETIC (PK) SAMPLE HANDLING

Evaluation	Response
<b>Have the following topics been discussed?</b> <b>Note: If no PK samples are required, indicate so in comments and use section to answer for clinical laboratory.</b>	
<b>a. has site been informed to inform CRA in case of change in reference ranges?</b>	<b>Yes</b>
<b>Comments :</b> Importance of sharing updated and latest lab reference ranges was emphasised during the discussion. Site was informed that lab reference ranges are already entered in the EDC by data management team of SIRO and hence site has to enter only the value of the lab test in the system.  Site was informed that incase of any change in the lab reference range, CRA must be informed immediately, as the updated information needs to be informed to the SIRO-DM team.  Site was told that timely information will avoid any unnecessary query generation from Data Management.	
<b>b. will site be maintaining a Test Requisition form for local lab samples?</b>	<b>Yes</b>
<b>Comments :</b> site was asked to prepare a TRF for the study to ensure none of the tests were missed to be performed at screening and EOS.	

## 14 AUDITS & INSPECTIONS

Evaluation	Response
<b>Have the following topics been discussed?</b>	
<b>a. Possibility of audits, regulatory inspections at the site</b>	<b>Yes</b>
<b>Comments :</b> None	





# SITE INITIATION REPORT

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<b>Site No.</b>	21	<b>Date of Visit</b>	03-Sep-2019
<b>Date of Last Visit</b>		<b>Visit No.</b>	SIV

## 15 INSTITUTIONAL REVIEW BOARD (IRB)/ INDEPENDENT ETHICS COMMITTEE (IEC) REQUIREMENTS

Evaluation	Response
<b>a. Was the site informed about the need for IRB/IEC approval of protocols, informed consents, all amendments and addenda, all other required documentation and any other written information provided to subjects?</b>	<b>Yes</b>
<b>Comments :</b> Site was informed about the possibility of Audit and/ or inspections and that Siro (CRO) and Torrent (Sponsor) team should be informed if any such information was made available to site directly.	
<b>b. If the investigator or any study team member is a member of the IRB/IEC, it must be documented that they abstained from deliberation/ voting.</b>	<b>Yes</b>
<b>Comments :</b> Site was aware of the need to obtain EC approval for any revision in the study documents like the protocol, ICF etc	
<b>c. A copy of the IRB/IEC approval for essential trial documents must be filed in the Site Master File</b>	<b>Yes</b>
<b>Comments :</b> None	
<b>d. Were the requirements of periodic updates to IRB/EC discussed?</b>	<b>Yes</b>
<b>Comments :</b> Site was advised to confirm the periodic update requirement on half yearly basis as stated in the EC SOP	

## 16 INVESTIGATOR SITE FILE

Evaluation	Response
<b>Have the following topics been discussed?</b>	
<b>a. ISF organization (including discussion of study specific logs and forms discussed with study personnel)</b>	<b>Yes</b>
<b>Comments :</b> ISF was organized during the visit with all original documents like CV, IU,PSP, EC communications filed in the respective sections. completion and filing of all logs and forms was also explained	
<b>b. Importance of maintaining the ISF up-to-date</b>	<b>Yes</b>
<b>Comments :</b> None	
<b>c. Were the documents as per ASD-CO-0054 filed in the ISF? (If any documents collected during the visit, please mention in comments)</b>	<b>No</b>
<b>Comments :</b> None	

## 17 ADEQUACY OF FACILITIES AT SITE AND SITE STAFF

Evaluation	Response
<b>Have the following topics been discussed/ facilities been visited?</b>	
<b>a. Clinical site facilities</b>	<b>Yes</b>



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## 17 ADEQUACY OF FACILITIES AT SITE AND SITE STAFF

<b>Evaluation</b>	<b>Response</b>
<b>Comments :</b> None	
<b>b. IP storage facilities</b>	<b>Yes</b>
<b>Comments :</b> None	
<b>c. Laboratory facilities</b>	<b>Yes</b>
<b>Comments :</b> None	
<b>d. Study records/ document storage facilities/ archival facilities</b>	<b>Yes</b>
<b>Comments :</b> None	
<b>e. Site staff adequate</b>	<b>Yes</b>
<b>Comments :</b> None	

## 18 STUDY CONTACTS

<b>Evaluation</b>	<b>Response</b>
<b>Have the following topics been discussed?</b>	
<b>a. All parties involved on behalf of sponsor who will interact with investigator site or provide support</b>	<b>Yes</b>
<b>Comments :</b> contact list was shared with site and also filed in the ISF	

## 19 FINANCIAL ASPECTS

<b>Evaluation</b>	<b>Response</b>
<b>Have the following topics been discussed?</b>	
<b>a. Financial aspects and terms of payments of investigator and procedures for raising invoice</b>	<b>Yes</b>
<b>Comments :</b> process of raising invoice was explained. post monitoring, CRA would inform site of visits/ patients monitored and according to the CTA, the completed visits would be paid against an original invoice form site.	
<b>b. Financial aspects and terms of payments of other parties in the study, e. g. laboratory, pharmacy etc. If yes, please specify under comments.</b>	<b>Yes</b>
<b>Comments :</b> As captured in the site specific ICF, a total of INR 500 shall be provided to the participating patients towards travel reimbursement as per site agreement. Site was advised to maintain supporting travel tickets and documents for inhouse fling.	
<b>c. Financial aspects and terms of payments for patient travel reimbursement</b>	<b>Yes</b>
<b>Comments :</b> None	





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<b>Date of Last Visit</b>		<b>Visit No.</b>	SIV

## 20 SITE CLOSE-OUT REQUIREMENTS

Evaluation	Response
<b>Have the following topics been discussed?</b>	
<b>a. Purpose of close-out visits. Requirements &amp; activities for site close-out, archival location and payment requirement for archival (if applicable)</b>	<b>Yes</b>
<b>Comments :</b> Archival period for the study documents post close out visit is planned for 5 years. Alternatively all the study documents may be archived at a Third Party Vendor approved by the sponsor. EC and site SOP/ policy, allows third party archival and the Site does not foresee any challenge as of now	
<b>b. Requirements for notification of study end</b>	<b>Yes</b>
<b>Comments :</b> The completion of the study shall be notified to the site EC.	

## 21 GENERAL COMMENTS

Evaluation	Response
<b>GENERAL COMMENTS</b>	<b>NA</b>
<b>Comments :</b> None	

## 22 STUDY MATERIAL

Evaluation	Response
<b>List study material provided to site before or at SIV</b>	<b>Yes</b>
<b>Comments :</b> Following were provided to site:  ISFs ICFs and patient questionnaires Stationary Source Notes IT access form Thermo hygrometers	

## 23 ACTION ISSUES

Evaluation	Response
<b>Were there any action items / issues observed or resolved during the visit</b>	<b>Yes</b>
<b>Comments :</b> None	



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## 24 SITE STATUS

<b>Evaluation</b>	<b>Response</b>
<b>SITE ACTIVATED i.e., allowed to start subject screening</b>	<b>Yes</b>
<b>Comments :</b> Site was initiated on 03Sep2019, however, the activation was done on 13Sep2019. The screening at the site started on 13-Sep -2019.	
<b>SITE NOT ACTIVATED for following reasons:</b>	<b>Yes</b>
<b>Comments :</b> None	

## Site Initiation Visit Report Review and Finalisation

<b>Author</b>		
<b>Prepared by</b>	Oza Jasmita	<b>e-Signature</b>
<b>Date of First Draft Submitted for Review</b>	16-Sep-2019	Oza Jasmita (jasmitao) / Mon Sep 16 2019 07:07:58 GMT-0000 (GMT) <b>Meaning of Signature :</b> Content Approval
<b>Reviewer(s)</b>		
<b>Reviewed by</b>	<b>Reviewed Date</b>	<b>e-Signature :</b>
Verma Mascha	23-Sep-2019	Verma Mascha (maschav) / Mon Sep 23 2019 07:24:20 GMT-0000 (GMT) <b>Meaning of Signature :</b> Management Approval
<b>Approver</b>		
<b>Approved by</b>	Verma Mascha	<b>e-Signature :</b>
<b>Approved Date</b>	23-Sep-2019	Verma Mascha (maschav) / Mon Sep 23 2019 07:24:20 GMT-0000 (GMT) <b>Meaning of Signature :</b> Management Approval





**MAHATMA GANDHI MISSION MEDICAL COLLEGE & HOSPITAL ,  
AURANGABAD**

**Academic Event Report**

Conferences/ Seminars/ CME/Workshop/ Quiz/ Debate/ Guest Lecture etc.

Date:- 09-11-2019

No.	Event Report
1.	Name & Level of Event – <i>College/ Regional/ State/ National/ International.</i>
<b>Site Initiation Visit , –Workshop, National level.</b>	
2.	Background/ Introduction – <i>Need/ reasons for holding the prg, Name of Association/ Collaboration etc.</i>
A Randomized, Open-label, Prospective, Comparative, Multi-centre, Parallel group, Active controlled, Phase III Study to Evaluate the Efficacy and Safety of the Ropivacaine Readyfusor 2mg/ml versus Ropivacaine Balloon Pump Infusor 2mg/ml as a continuous surgical site infusion for the Treatment of Post-Surgical Pain in lower abdominal laparotomy	
3.	Venue -
• Pharmacology Department , MGM Medical college AURANGABAD	
4.	Sponsors – <i>Name &amp; details If any</i>
Cipla Ltd/JSS CRO.	
5.	Inauguration – <i>including the details of Chief Guest, Guest(s) of Honor, gist of speeches given, compared by etc.....</i>
• CHIEF GUEST: - Dr. Vasanti Kelkar, Dr. Shubhangi Mande , Dr. Sanhita Kulkarni ,Dr. Palak Bohra. Compared: - Dr. Deepak Bhosle.	
6.	Speakers/ Judges/ Chairman/ Panel Team – <i>Brief introduction with their achievements.</i>
Speakers : <ul style="list-style-type: none"><li>• Dr. Deepak Bhosle (HOD Pharmacology, MGM Medical College, Aurangabad)</li><li>• Dr. Vasanti Kelkar ( Principal Investigator, MGM Medical College, Aurangabad)</li><li>• Ankita Singh (Assistant Project Manager, JSS Medical Research)</li><li>• Dr. Sonali Jadhav (Deputy Manager Medical and Safety Expert, Cipla Ltd)</li><li>• Khushbu Shah (Clinical Research Associate, JSS Medical Research)</li></ul>	
7.	Participants & Delegates – <i>No of participants &amp; delegates/ teams with their names.</i>
All Study staff	
8.	Prize Distribution etc – <i>Brief Summary of the Proceeding</i>





**MAHATMA GANDHI MISSION MEDICAL COLLEGE & HOSPITAL ,  
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**Academic Event Report**

Conferences/ Seminars/ CME/Workshop/ Quiz/ Debate/ Guest Lecture etc.

**9.** **Valedictory Ceremony – Brief of the proceedings including chief guest etc and who conducted it.**

**10.** **Highlights of the Event – Brief about the main highlight(s) of the event.**

- Site Staff, Facilities and Study Supplies
- Compliance to Protocol/Amendment(s) and regulatory requirements
- Subject Recruitment & Enrollment
- Informed Consent Procedures/Process
- Case Report Form (CRF) / Electronic Case Report Form (eCRF) Requirements
- Data Entry and Query Resolution Timelines
- Monitoring Procedures
- IP storage and accountability
- Laboratory Procedures and Biological Samples
- Essential Documents and ISF review

**Professor & Head  
Pharmacology Department  
MGM Medical College & Hospital, Aurangabad**



**To,**  
Dr. Vasanti Kelkar,  
Associate Professor  
Department of Anesthesiology,  
Mahatma Gandhi Mission's Medical College and Hospital,  
N-6 Cidco, Aurangabad-431003

**Date: 07 Nov 2019**

**Reference:** CP/04/18: A Randomized, Open-label, Prospective, Comparative, Multi-centre, Parallel group, Active controlled, Phase III Study to Evaluate the Efficacy and Safety of the Ropivacaine Readyfusor 2mg/ml versus Ropivacaine Balloon Pump Infusor 2mg/ml as a continuous surgical site infusion for the Treatment of Post-Surgical Pain in lower abdominal laparotomy.

**Subject:** Confirmation letter of Site initiation visit on **09 Nov 2019**

Dear Dr. Kelkar,

Thank you for confirming the Site initiation visit (SIV) at your esteemed site. I and Ms. Ankita Singh (Assistant Project Manager, JSS Medical Research) will arrive at your site on 09 Nov 2019, Saturday at 09:30 hrs for the above referenced Study. Dr. Sonali Jadhav (Deputy Manager Medical and Safety Expert) Sponsor representative will accompany for the SIV. The visit will last for One day.

In order to accomplish these objectives, I request that the following site personnel be available for the visit:-

Sr. No.	Name	Role in Study
1.	Dr. Vasanti Prabhakar Kelkar	Principal Investigator
2.	Dr.Sanhita Kulkarni Jiten	Co- Investigator
3.	Dr.Shubhangi Arunrao Mande	Co- Investigator
4.	Dr. Bohra Palak Rajendra	Co- Investigator
5.	Mr. Shaikh Yahiya Ali	Clinical Research Coordinator

During the visit, we will accomplish the following:-

1. Study Overview and Timelines
2. Protocol Overview
3. Screening/ Enrollment expectations
4. Investigational Product Management
5. Randomization Process
6. Consenting the patient:
  - Importance of obtaining the informed consent before any study related procedures are performed
  - Using the appropriate EC approved versions

- Consenting procedure for illiterate patients
  - Filing of Informed Consent Forms
7. CRF completion and verification/retrieval
  8. Safety management
  9. Investigator Site File overview
  10. Source Documentation & Patient Flow
  11. ICH GCP, New CT Rules 2019, Monitoring Expectations

Following supplies have been dispatched to your site prior to this visit:

Sr. No.	Items	Quantity
01	Investigator Trial Master File (Binder 1 & Binder 2)	02
02	Study Binder-ICF	01
03	Study logs Binder	01
04	Ropivacaine Readyfusor 2mg/ml solution for infusion in administration system with other related supplies packet in box	06
05	Baxter Balloon Pump box with other related supplies packet in box	03
06	Aquamol Paracetamol Injection	36
07	HTC Thermo Hygrometer with Calibration certificate	01
08	Ropin 0.75 % Injection 20 ml	09
09	Randomization Envelope	09

For clarification/ support, please contact me at +91 9152240585 or khushbu.shah@jssresearch.com

Thank you for your cooperation and continuous efforts for the study.

I thank you in advance for your time and look forward to meeting you & the site team.

Sincerely,

*Khushbu Shah*  
07 NOV 2019

Ms. Khushbu Shah  
Clinical Research Associate

Cc: Project Incharge  
Project Management File – Site

Acknowledgment	
Name: Dr. V. P. Kelkar	09/11/2019
Signature: <i>Dr. V. P. Kelkar</i>	Signature date





MAHATMA GANDHI MISSION MEDICAL COLLEGE & HOSPITAL,  
AURANGABAD

### Academic Event Report

Conferences/ Seminars/ CME/Workshop/ Quiz/ Debate/ Guest Lecture etc.

Date:- 14-10-2019

No.	Event Report
1.	Name & Level of Event – <i>National</i>
	<b>Site Initiation Visit , –Workshop, National level.</b>
2.	Background/ Introduction – <i>Need/ reasons for holding the prg, Name of Association/ Collaboration etc.</i>
	Protocol Number:- CTQJ230A12001 Title:- Multi-centre cross-sectional epidemiological study to characterize the prevalence and distribution of lipoprotein (a) levels among patients with established cardiovascular disease.
3.	Venue -
	<ul style="list-style-type: none"><li>• Pharmacology Department , MGM Medical college AURANGABAD</li></ul>
4.	Sponsors – <i>Name &amp; details If any</i>
	<b>NOVARTIS</b>
5.	Inauguration – <i>including the details of Chief Guest, Guest(s) of Honor, gist of speeches given, compared by etc.....</i>
	<ul style="list-style-type: none"><li>• CHIEF GUEST: -</li><li>• Dr Prashant Udgire, Dr Abhinav Chhabda, Dr Rahul Patne, Dr Richa Rajput</li></ul> Compared: - Dr. Deepak Bhosle.
6.	Speakers/ Judges/ Chairman/ Panel Team – <i>Brief introduction with their achievements.</i>
	Speaker: <ul style="list-style-type: none"><li>• Neha Srivastava (Clinical Research Associate, NOVARTIS)</li><li>• Dr. Deepak Bhosle- Professor &amp; Head, Pharmacology Department</li><li>• Dr Prashant Udgire-Associate Prof. Dept of Cardiology</li></ul>
7.	Participants & Delegates – <i>No of participants &amp; delegates/ teams with their names.</i>
	<b>All Study staff</b>
8.	Prize Distribution etc – <i>Brief Summary of the Proceeding</i>
9.	Valedictory Ceremony – <i>Brief of the proceedings including chief guest etc and who</i>





**MAHATMA GANDHI MISSION MEDICAL COLLEGE & HOSPITAL ,  
AURANGABAD**

**Academic Event Report**

Conferences/ Seminars/ CME/Workshop/ Quiz/ Debate/ Guest Lecture etc.

conducted it.

**10.**

**Highlights of the Event – Brief about the main highlight(s) of the event.**

- Site Staff, Facilities and Study Supplies
- Compliance to Protocol/Amendment(s) and regulatory requirements
- Subject Recruitment & Enrollment
- Informed Consent Procedures/Process
- Case Report Form (CRF) / Electronic Case Report Form (eCRF) Requirements
- Data Entry and Query Resolution Timelines
- Monitoring Procedures
- Laboratory Procedures and Biological Samples
- Essential Documents and ISF review.

**Professor & Head  
Pharmacology Department  
MGM Medical College & Hospital, Aurangabad**





**MAHATMA GANDHI MISSION MEDICAL COLLEGE & HOSPITAL ,  
AURANGABAD**

**Academic Event Report**

Conferences/ Seminars/ CME/Workshop/ Quiz/ Debate/ Guest Lecture etc.

08 -Jan -2020

No.	Event Report
1.	<b>Name &amp; Level of Event – College/ Regional/ State/ National/ International.</b>  <b>Site Initiation Visit , –Workshop, National level.</b>
2.	<b>Background/ Introduction – Need/ reasons for holding the prg, Name of Association/ Collaboration etc.</b>  “A prospective , multicenter, randomized, double – blind, phase 3 study to Evaluate the Safety and Efficiency of a Gel formulation of Esmolol Hydrochloride (Galnobax®) In Treating Dibetic Foot Ulcer”
3.	<b>Venue -</b>  • <b>Pharmacology Department , MGM Medical college AURANGABAD.</b>
4.	<b>Sponsors – Novalade Pharma</b>  <b>JSS CRO</b>
5.	<b>Inauguration – including the details of Chief Guest, Guest(s) of Honor, gist of speeches given, compared by etc.....</b>  • <b>CHIEF GUEST: - Dr.Deepak Bhosle, Dr.Tejiindersingh Chhabda, Dr.Amey Chakkarwad, Dr. Snehal Chawan.</b> <b>Compared: - Dr. Deepak Bhosle.</b>
6.	<b>Speakers/ Judges/ Chairman/ Panel Team – Brief introduction with their achievements.</b>  <b>Speakers :</b> <ul style="list-style-type: none"><li>• <b>Rucha (Clinical Research Associate, Blinded, JSS)</b></li><li>• <b>Kavita (Clinical Research Associate, Unblinded, JSS)</b></li></ul>
7.	<b>Participants &amp; Delegates – No of participants &amp; delegates/ teams with their names.</b>  <b>All Study staff</b>





**MAHATMA GANDHI MISSION MEDICAL COLLEGE & HOSPITAL ,  
AURANGABAD**

**Academic Event Report**

Conferences/ Seminars/ CME/Workshop/ Quiz/ Debate/ Guest Lecture etc.

**8. Prize Distribution etc – Brief Summary of the Proceeding**

**9. Valedictory Ceremony – Brief of the proceedings including chief guest etc and who conducted it.**

**10. Highlights of the Event – Brief about the main highlight(s) of the event.**

- Site Staff, Facilities and Study Supplies
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- IP storage and accountability
- Laboratory Procedures and Biological Samples
- Essential Documents and ISF review

**Professor & Head  
Pharmacology Department  
MGM Medical College & Hospital, Aurangabad**



Date: 28 Jan 2020

To  
Dr. Deepak Sadashiv Bhosle  
Department of Pharmacology,  
Mahatma Gandhi Mission's (MGM)  
Medical College and Hospital,  
N-6, Cidco, Aurangabad- 431003

**Protocol No:** NG-A16

**Protocol Title::** A Prospective, Multicenter, Randomized, Double-Blind, Phase 3 Study to Evaluate the Safety and Efficacy of a Gel Formulation of Esmolol Hydrochloride (Galnobax®) in Treating Diabetic Foot Ulcers.

**Subject:** Follow up Letter for the Site Initiation Visit conducted on 7-8 Jan 2020

**Dear Dr. Bhosle,**

It was pleasure meeting with you and your's study team members on 7-8 Jan 2020 to conduct the initiation visit for above mentioned Study.

The primary purpose of this visit was to train you and your staff on the Protocol specific study procedures:

The following items were reviewed during the visit,

1. Study Overview and Timelines
2. Protocol Overview
3. Screening/ Enrollment expectations
4. Investigational Product Management
5. Consenting the patient:
  - Importance of obtaining the informed consent before any study related procedures are performed
  - Using the appropriate EC approved versions
  - Filing of Informed Consent Forms
6. Laboratory specimen collection storage and shipment
7. CRF completion and verification/retrieval
8. Adverse Event recording and reporting
9. Familiarization of safety reporting formats and procedures/guidelines
10. Regulatory Documents & Investigator Site File overview
11. Visit to site facilities
12. Source Documentation & Patient Flow
13. ICH GCP, Schedule Y, Monitoring Expectations

Confidential and Proprietary to JSS Medical Research India Private Limited

Study: NG-A16

Site: MGM Hospital Aurangabad

Site Initiation Visit Follow Up Letter

JSS-MN-03 v.12.0 - Annexure XIX

JSS Medical Research India Private Limited

Branch Office: No. 406 & 407, 4th Floor, C2 Skyline Wealth Spaces, Skyline Oasis Building #3, Wing C2, Vihar, Vikhroli (W), Mumbai - 400 086. Tel: +91-022-2512 6782 / 83, CIN: U74999HR1999PTC0181

Registered Office: Plot No. 12/2, 6th Floor, Vatika Mindscapes Tower-B, Sector-27D, Faridabad-121003, Haryana-India

As a follow-up to this visit the action items for the site are as follows,

Sr. No.	Issue description	Action	Action by whom e.g. PI, SI, CRC	Status (Open/ Closed; if open mention expected date of resolution)
1.	CV & MRC and GCP Certificate of Dr. Chhabada (Un Blinded Sub I) and CV and GCP certificate of Dr. Amit , Dr. Snehal	CRC to be share the copy of the same with CRA	CRC & Sub I	Open/ 4 <sup>th</sup> Week of Jan 2020
2.	Accreditation Certificate of local Lab	CRC to provide copy of the same	CRC	Open/ 4 <sup>th</sup> Week of Jan 2020
3.	Copy of the CDA to be shared with monitor & ISF to be updated accordingly	CRC to provide the copy of the same	CRC	Open/ 4 <sup>th</sup> Week of Jan. 2020
4.	FDF to be completed for Dr. Chhabada, Dr. Amit & Dr. Snehal	CRC to provide the copy of the same with monitor	CRC & Sub I's	Open/ 4 <sup>th</sup> Week of Jan 2020
5.	Calibration Certificates of deep freezer, ECG, Centrifuge, Thermohydrometer etc.	CRC to provide the copy of the same with monitor	CRC	Open/ 4 <sup>th</sup> Week of Jan 2020

As a follow-up to this visit the action items for the CRA/ JSS India are as follows,

Sr. No.	Issue description	Action	Action by whom e.g Sponsor, PrI, CRA, MM	Status (Open/ Closed; if open mention expected date of resolution)
1.	Follow up with the site team to close all the open action item	Contact the CRC and get the action items closed	CRA	Open/ 4 <sup>th</sup> Week of Jan 2020
2.	To share the SIV Report and the Follow up letter to site (With in timeline)	To prepare the report and Follow up letter	CRA	Open/ 4 <sup>th</sup> Week of Jan 2020

I would also like to thank you & your study team for the availability during the visit.

If you should have additional questions regarding the initiation visit or study, please contact me at +91-9820120836/02225126782 or email at [rucha.paretkar@jssresearch.com](mailto:rucha.paretkar@jssresearch.com)



I look forward to your kind cooperation & support.

Sincerely,

*RD Paretkar*  
*28 Jan 2020*

Ms. Rucha Paretkar  
Clinical Research Associate

Cc: Project Management File - Site

Acknowledgment	
Name: <i>Linpadmaja Thakur</i>	Signature date: <i>24 Feb 2020</i>
Signature: <i>Linpadmaja</i>	





**MAHATMA GANDHI MISSION MEDICAL COLLEGE & HOSPITAL ,  
AURANGABAD**

**Academic Event Report**

Conferences/ Seminars/ CME/Workshop/ Quiz/ Debate/ Guest Lecture etc.

Date:- 10- Jan -2020

No.	Event Report
1.	<b>Name &amp; Level of Event – College/ Regional/ State/ National/ International.</b>  <b>Site Initiation Visit , –Workshop, National level.</b>
2.	<b>Background/ Introduction – Need/ reasons for holding the prg, Name of Association/ Collaboration etc.</b>  “A Prospective, Double-blind, Randomization parallel-Group, vehicle-controlled, Multicenter study to Evaluate the safety and Bioequivalence of Mupirocin cream USP2% (Supplied by: Glasshouse Pharmaceuticals Limited Canada) using Mupirocin cream USP2% (Manufactured by: Glenmark Pharmaceuticals Inc; USA ) as a Reference product, in subjects with secondarily Infected Traumatic Skin Lesion.
3.	<b>Venue -</b>  • <b>Pharmacology Department , MGM Medical college AURANGABAD</b>
4.	<b>Sponsors – Glasshouse</b>  <b>JSS CRO</b>
5.	<b>Inauguration – including the details of Chief Guest, Guest(s) of Honor, gist of speeches given, compared by etc.....</b>  • <b>CHIEF GUEST: - Dr. Ashish Deshmukh, Dr. Snehal Salwe</b> <b>Compared: - Dr. Deepak Bhosle.</b>
6.	<b>Speakers/ Judges/ Chairman/ Panel Team – Brief introduction with their achievements.</b>  <b>Speakers :</b> <ul style="list-style-type: none"><li>• <b>Mr. Himanshu Jain (Clinical trial Manager, Glasshouse, Canada )</b></li><li>• <b>Dr. Inderpreet Kaur ( Project Manager, JSS India)</b></li><li>• <b>Dr. Vishal Dinde (Clinical Research Associate, JSS)</b></li></ul>





**MAHATMA GANDHI MISSION MEDICAL COLLEGE & HOSPITAL ,  
AURANGABAD**

**Academic Event Report**

Conferences/ Seminars/ CME/Workshop/ Quiz/ Debate/ Guest Lecture etc.

**7.** **Participants & Delegates – No of participants & delegates/ teams with their names.**

All Study staff

**8.** **Prize Distribution etc – Brief Summary of the Proceeding**



**9.** **Valedictory Ceremony – Brief of the proceedings including chief guest etc and who conducted it.**


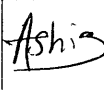


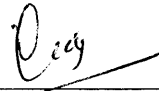

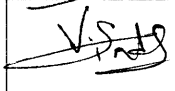

**10.** **Highlights of the Event – Brief about the main highlight(s) of the event.**

- Site Staff, Facilities and Study Supplies
- Compliance to Protocol/Amendment(s) and regulatory requirements
- Subject Recruitment & Enrollment
- Informed Consent Procedures/Process
- Case Report Form (CRF) / Electronic Case Report Form (eCRF) Requirements
- Data Entry and Query Resolution Timelines
- Monitoring Procedures
- IP storage and accountability
- Laboratory Procedures and Biological Samples
- Essential Documents and ISF review

*Handwritten signature*

**Professor & Head  
Pharmacology Department  
MGM Medical College & Hospital, Aurangabad**

		<b>JSS Medical Research India Private Limited Monitoring</b>			
<b>Form Title: Site Visit Log</b>					
SOP Number: JSS-MN-03		Current Document Version Number: 1.0		Previous Document Version Number: None	
Document Date: 29 Nov 2019		Sponsor Name: Glasshouse Pharmaceuticals Limited Canada		Site Name: Mahatma Gandhi Mission Medical College & Hospital	
Site Number: 04		Site Address: MGM Medical College & Hospital, N-6, cidco, Aurangabad, 431003, Maharashtra		Protocol No: GH-SL-IN-01	
Investigators Name: Dr. Ashish Deshmukh		Protocol Title: A Prospective, Double-blind, Randomized, Parallel-Group, Vehicle-Controlled, Multicenter Study to Evaluate the Safety and Bioequivalence of Mupirocin Cream USP 2% (Supplied by: Glasshouse Pharmaceuticals Limited Canada) using Mupirocin Cream USP 2% (Manufactured by: Glenmark Pharmaceuticals Inc; USA) as a Reference Product, in Subjects with Secondarily Infected Traumatic Skin Lesions			

Sr. No.	Date	Type of Visit*	Name of Monitor/Sponsor Representative	Monitor/Sponsor representative		Principal Investigator/Sub Investigator	
				Signature	Date	Signature	Date
01	10 Jan 2020	SIV	Meeng Dalal		10 JAN 2020		10 Jan 2020
02	10 JAN 2020	SIV	HIRANSHU JAIN		10 JAN 2020		10 Jan 2020
03	10 JAN 2020	SIV	Dr. Inderpreet Kaur		10 JAN 2020		10 Jan 2020
04	10 Jan 2020	SIV	Dr. Vishal Dinde		10 Jan 2020		10 Jan 2020

\*PSSV= Pre-study Site Selection Visit, SIV = Site Initiation Visit, IMV = Interim Monitoring Visit, SCV = Site Close out Visit, Others = Audit, Comonitoring etc.

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**MAHATMA GANDHI MISSION MEDICAL COLLEGE & HOSPITAL ,  
AURANGABAD**

**Academic Event Report**

Conferences/ Seminars/ CME/Workshop/ Quiz/ Debate/ Guest Lecture etc.

Date:- 07-02-2020

No.	Event Report
1.	<b>Name &amp; Level of Event – College/ Regional/ State/ National/ International.</b>  <b>Site Initiation Visit , –Workshop, National level.</b>
2.	<b>Background/ Introduction – Need/ reasons for holding the prg, Name of Association/ Collaboration etc.</b>  “A comparative, randomized, two arm, double blind, parallel group, multicentric, phase III clinical study to evaluate the efficacy, safety and tolerability of Netarsudil ophthalmic solution 0.02% w/v versus Timolol Maleate eye drops 0.5% w/v in treatment of elevated intraocular pressure (IOP) in subjects with open angle glaucoma or ocular hypertension.”
3.	<b>Venue -</b>  • Pharmacology Department, MGM Medical College, Aurangabad
4.	<b>Sponsors – Name &amp; details If any</b>  Ajanta Pharma /Mediclin CRO.
5.	<b>Inauguration – including the details of Chief Guest, Guest(s) of Honor, gist of speeches given, compared by etc.....</b>  • <b>CHIEF GUEST:</b> - Dr. Jyotika Mishrikotkar, Dr. Yogita Phadke, Dr. Rujuta Sapkal <b>Compared:</b> - Dr. Deepak Bhosle.
6.	<b>Speakers/ Judges/ Chairman/ Panel Team – Brief introduction with their achievements.</b>  <b>Speakers :</b>  • Dr. Deepak Bhosle (HOD Pharmacology, MGM Medical College, Aurangabad) • Dr. Jyotika Mishrikotkar (HOD Ophthalmology, MGM Medical College, Aurangabad) • Ashish Malap (Clinical Research Associate, Mediclin CRO)
7.	<b>Participants &amp; Delegates – No of participants &amp; delegates/ teams with their names.</b>





**MAHATMA GANDHI MISSION MEDICAL COLLEGE & HOSPITAL ,  
AURANGABAD**

**Academic Event Report**

Conferences/ Seminars/ CME/Workshop/ Quiz/ Debate/ Guest Lecture etc.

**All Study staff**

**8. Prize Distribution etc – Brief Summary of the Proceeding**

**9. Valedictory Ceremony – Brief of the proceedings including chief guest etc and who conducted it.**

**10. Highlights of the Event – Brief about the main highlight(s) of the event.**

- Site Staff, Facilities and Study Supplies
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- Laboratory Procedures and Biological Samples
- Essential Documents and ISF review

**Professor & Head  
Pharmacology Department  
MGM Medical College & Hospital, Aurangabad**



Subject: Fwd: RIS 1st Investigators meeting site presentation template

----- Forwarded message -----

From: **VARSHA SUDHIR CHAUDHARY** <[varsha.sudhir@cmcvellore.ac.in](mailto:varsha.sudhir@cmcvellore.ac.in)>

Date: Mon, Mar 2, 2020 at 2:29 PM

Subject: Re: RIS 1st Investigators meeting site presentation template

To: haseeb mohd <[mohdhaseeb181@gmail.com](mailto:mohdhaseeb181@gmail.com)>, [drmadhuriengade@gmail.com](mailto:drmadhuriengade@gmail.com)  
<[drmadhuriengade@gmail.com](mailto:drmadhuriengade@gmail.com)>

Cc: wellcome <[wellcome@cmcvellore.ac.in](mailto:wellcome@cmcvellore.ac.in)>, Prasanna Samuel  
<[prasanna.samuel@cmcvellore.ac.in](mailto:prasanna.samuel@cmcvellore.ac.in)>, Venkata Raghava <[venkat@cmcvellore.ac.in](mailto:venkat@cmcvellore.ac.in)>, gkang  
<[gkang@cmcvellore.ac.in](mailto:gkang@cmcvellore.ac.in)>, GAYATHRI S <[gayathri.s@cmcvellore.ac.in](mailto:gayathri.s@cmcvellore.ac.in)>

Dear Dr Haseeb/Dr Madhuri,

As discussed, please find attached the logbook and case report form as well as the guidelines to fill the same for RIS study. The Parent Information sheet (PIS) and Informed Consent Form (ICF) as shared in Hindi and Marathi earlier may be used as such.

Request you to initiate the enrolment and data collection for all eligible cases admitted from the date of EC approval at MGMC, Aurangabad (07.02.2020). Consent for discharged cases will need to be taken from their homes in the current date.

Kindly let us know if you have any queries.

Regards

Dr Varsha Chaudhary Co-Investigator-RIS  
The Wellcome Trust Research Laboratory  
Division of Gastrointestinal Sciences  
Christian Medical College, Vellore TN 632004 India  
Mob +919930032195

---

**From:** VARSHA SUDHIR CHAUDHARY

**Sent:** 02 March 2020 11:05

**To:** haseeb mohd; [drmadhuriengade@gmail.com](mailto:drmadhuriengade@gmail.com)

**Cc:** wellcome; Prasanna Samuel; Venkata Raghava; gkang; GAYATHRI S

**Subject:** RIS 1st Investigators meeting site presentation template

Dear Dr Haseeb/ Dr Madhuri,

Please find attached the template for a 5 minute site presentation from MGMC, Aurangabad at the 1st investigators meeting on March 13th 2020.

Kindly fill in the necessary details and share the presentation for compilation at the earliest.

Regards

Dr Varsha Chaudhary  
Co-Investigator-RIS  
The Wellcome Trust Research  
Laboratory  
Division of Gastrointestinal Sciences  
Christian Medical  
College, Vellore  
TN 632004 India  
Mob +919930032195

--- Attachment: RIS Guidelines to fill paper Logbook Feb2020.pdf ---

--- Attachment: RIS Instructions to fill paper CRF Feb2020.pdf ---

--- Attachment: RIS Paper CRF Feb2020.pdf ---



--- Attachment: RIS paper Logbook Feb2020.pdf ---





**MAHATMA GANDHI MISSION MEDICAL COLLEGE & HOSPITAL ,  
AURANGABAD**

**Academic Event Report**

Conferences/ Seminars/ CME/Workshop/ Quiz/ Debate/ Guest Lecture etc.

Date:- 18-02-2020

No.	Event Report
1.	Name & Level of Event – College/ Regional/ State/ National/ International.  <b>Site Initiation Visit , –Workshop, National level.</b>
2.	Background/ Introduction – Need/ reasons for holding the prg, Name of Association/ Collaboration etc.  “A Phase III, Multicentre, Randomized, Double Blind, Parallel group, Comparative Clinical Study to evaluate Efficacy and Safety of Ropivacaine Hydrochloride 0.75% (7.5mg/mL) in Dextrose 8% (80mg/mL) injection compared to Bupivacaine Hydrochloride 0.5% (5mg/mL) in Dextrose 8% (80mg/mL) injection for subjects undergoing lower limb orthopaedic surgeries under spinal anesthesia”
3.	Venue -  • Pharmacology Department , MGM Medical college AURANGABAD
4.	Sponsors – Name & details If any  NEON LABORATORIES LTD/ Biosphere CRO
5.	Inauguration – including the details of Chief Guest, Guest(s) of Honor, gist of speeches given, compared by etc.....  • CHIEF GUEST: - Dr. Vasanti Kelkar, Dr. Pradnya Kulkarni Compared: - Dr. Deepak Bhosle.
6.	Speakers/ Judges/ Chairman/ Panel Team – Brief introduction with their achievements.  Speakers : • Dr. Deepak Bhosle (HOD Pharmacology, MGM Medical College, Aurangabad) • Hitesh Kachave (Clinical Research Associate, Biosphere CRO)
7.	Participants & Delegates – No of participants & delegates/ teams with their names.





**MAHATMA GANDHI MISSION MEDICAL COLLEGE & HOSPITAL ,  
AURANGABAD**

**Academic Event Report**

Conferences/ Seminars/ CME/Workshop/ Quiz/ Debate/ Guest Lecture etc.

All Study staff

**8. Prize Distribution etc – Brief Summary of the Proceeding**

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- Essential Documents and ISF review

**Professor & Head  
Pharmacology Department  
MGM Medical College & Hospital, Aurangabad**





# Biosphere Clinical Research Pvt. Ltd.

Date-27/02/2020

**TO,**

Dr. Vasanti Kelkar  
Department of Pharmacology  
4<sup>th</sup> floor, MGM Medical College and Hospital  
N-6 Cidco, Aurangabad. 431003  
Maharashtra, India.

**Site-** M.G.M. medical college and Hospital.

**Protocol ID-** BCR-RPD-01

**Protocol Title-** "A Phase III, Multicentre, Randomized, Double Blind, Parallel group, Comparative Clinical Study to evaluate Efficacy and Safety of Ropivacaine Hydrochloride 0.75% (7.5mg/mL) in Dextrose 8% (80mg/mL) injection compared to Bupivacaine Hydrochloride 0.5% (5mg/mL) in Dextrose 8% (80mg/mL) injection for subjects undergoing lower limb orthopaedic surgeries under spinal anaesthesia."

**Subject:** Site Initiation Visit Follow-up Letter

Respected Dr. Kelkar

It was a pleasure meeting you and your site study staff in preparation for the above-referred study. I would like to thank you and your study staff for the time and attention extended to us during the Site Initiation visit on 18-Feb-2020.

During the visit the following items were discussed:

**1. Introduction**

CRA would be primary contact person on behalf of the CRO and sponsor Neon laboratories Ltd. for the referenced clinical study.

**2. Protocol Discussion:**

Protocol (version 2.0 dated 19-Sep-2019) was presented during the visit, which included objectives & rationale, inclusion/exclusion criteria, study flow chart, treatment groups, enrolment procedure, randomisation, and timelines for screening and randomization, visit schedule, procedures for subject/study discontinuation, study progress updates, and archival requirements, etc. were discussed with the principal investigator and the study site staff.





# Biosphere Clinical Research Pvt. Ltd.

## 3. Informed Consent Process and Enrolment

Informed Consent document English version 2.0 dated 19-Sep-2019 and translated languages of ICF (Marathi and Hindi) and procedure for obtaining informed consent, enrolment procedure and timelines for screening and randomization was explained to the principal investigator and the study site staff. The site team was also trained on documenting the consent narrative. The site team was instructed to provide a copy of site informed consent document to the subject.

## 4. Patient Recruitment and Retention

Patient recruitment and retention as per protocol was explained to the principal investigator and the study site staff. Principal investigator assured to enrol 24 subjects in the trial.

## 5. Study Drug Dispensing, Accountability and Management

The site has received 28 kits of IMP which are adequate to initiate the recruitment and if additional kits are required during course of the study, it will be resupplied on receipt of resupply request from the site.

Storage area for IMP and other supplies storage were inspected and confirmed that the IMP is stored in restricted access to study team members and at the temperature should be in between 15-25<sup>o</sup> C.

I discussed IMP storage, dispensing, return by the subjects, reconciliation, retrieval and destruction, reordering of supplies, etc. as per study protocol version 2.0 dated 19-Sep-2019. The site coordinator was instructed to inform the study monitor immediately in case of temperature excursion and any issues related to the IMP.

## 6. AE and SAE Reporting process

Training on recording, analyzing and reporting of AEs and SAEs as per ICH and guidelines has been provided during the visit. The responsibilities of the principal investigator and other study site staff regarding AE and SAE reporting with timelines were explained to the site team. The site team was also trained in detail regarding the completion of the SAE reporting form.

## 7. Investigator Site File maintenance

Site was trained on the discussed the procedure for updating and maintenance of the Investigator's Site File. The site team was also trained on completion of all the logs and forms used in the study and also instructed that the logs should be completed and updated from time to time.

## 8. Source Documentation process (Good Documentation Practices)

CRA informed site staff that the source data, essential documents and CRFs must be completed and made available for verification by the site staff to monitor prior to the visit. CRA also informed that study documentation should only be completed by the designated personnel as listed in the study duty delegation log. The designated study site staff should be available during the monitoring visit.



# Biosphere Clinical Research Pvt. Ltd.

## 9. Study Supplies

CRA handed over the completed Investigator's site file to the Investigator and study site staff and confirmed that the file was kept at its designated place with access only to the study team members.

All trial related supplies including locked cupboards, study documents, etc. were present at your site.

All the study specific materials i.e. PIS-ICF, drug dosing card, source document template, study related logs and questionnaires etc. and their quantities were adequate and appropriately stored in research room at the site with restricted access to the study team members.

## 10. CRF Completion Training

Case report form, instructions for its completion/correction and transmittal were explained to study site staff during the visit.

## 11. Study Monitoring Plan

Tentative schedule for monitoring visit was discussed with the PI and the site staff. I informed that the first monitoring visit will be scheduled within 15 days of the first patient being randomized at the site and the subsequent visits will be between 6-8 weeks. The frequency of monitoring visits may vary depending on the number of subject enrolled at the site. Each monitoring visit will be for 1-2 days and a detailed agenda will be sent to the site before the scheduled visit after confirmation with the site.

CRA also discussed the possibility of sponsor audit and regulatory inspection at your site. Site team was informed that the study documents should be made available to the auditors and inspectors during the audits and inspections.

## 12. Study Conduct and Site Personnel Responsibilities

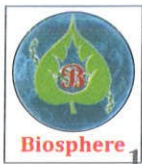
CRA obtained the Site Visit Log, Duty Delegation Log, Site Personnel Training Log and SIV Attendance Log from the investigator/study site staff. CRA informed site staff, if a new member is added to the site team the log must be updated immediately and a copy of the same should be forwarded to the monitor.

## 13. Administration

CRA trained the study site staff about maintaining the protocol compliance, retention of all study specific records and maintenance of the records related to investigational product.

CRA informed the site team that he will be the primary contact person for the study, contact details were provided to the site during the visit.





# Biosphere Clinical Research Pvt. Ltd.

## 14. ICH GCP and Schedule Y

CRA trained PI and site staff on ICH GCP guidelines, clinical trial rules 2019 and Schedule Y guidelines and principles for the conduct of clinical trials.

## 15. Site Tour: Confirmation of Facilities

CRA conducted a tour of site including OPD room, laboratory facilities, clinical research department, etc. CRA observed that found that the site was equipped with computer, centrifuge, refrigerator, scanner, printer, cupboard, temperature-controlled facility for IP storage and other study specific requirements. Site also has the required internet connection. It was confirmed that site has all the facilities and infrastructure required for the conduct of this study at the site.

## 16. Site Actions:

I would like to draw your attention towards action items which were discussed with you during closing meeting.

1. To provide scanned copy of IMP receipt acknowledgment.
2. CV, MRC, and GCP of all staff present on duty delegation log.
3. Kindly notify EC on below mentioned documents and share the acknowledgement at the earliest.
  - CTRI registration
  - Fully executed CTA

The next visit to your site will be within 15 days of randomization of your first patient.

In the meantime, should you have any further questions please do not hesitate to contact me at "+91-9833955150" or via email at "hitesh.k@biospherecro.com"

Yours sincerely,

Mr. Hitesh Kachave  
Clinical Research Associate  
Biosphere Clinical Research Pvt. Ltd.  
Thane-400607, Maharashtra, India.





**MAHATMA GANDHI MISSION MEDICAL COLLEGE & HOSPITAL ,  
AURANGABAD**

**Academic Event Report**

Conferences/ Seminars/ CME/Workshop/ Quiz/ Debate/ Guest Lecture etc.

Date:- 11-05-2020

No.	Event Report
1.	<b>Name &amp; Level of Event – College/ Regional/ State/ National/ International.</b>
	<b>Site Initiation Visit , –Workshop, National level.</b>
2.	<b>Background/ Introduction – Need/ reasons for holding the prg, Name of Association/ Collaboration etc.</b>
	A multicenter, phase III, double-blind, randomized, placebo-controlled study to evaluate the efficacy of recombinant BCG VPM1002 in reducing infection incidence and disease severity of sars-cov-2/covid-19 among high-risk subjects.’
3.	<b>Venue -</b>
	<ul style="list-style-type: none"><li>• Online</li></ul>
4.	<b>Sponsors – Name &amp; details If any</b>
	<b>Serum Institute of india /Diagnosearch CRO.</b>
5.	<b>Inauguration – including the details of Chief Guest, Guest(s) of Honor, gist of speeches given, compared by etc.....</b>
	<ul style="list-style-type: none"><li>• <b>CHIEF GUEST: - Dr. Deepak Tayade, Dr. Bhavana Joshi , Dr. Shraddha Kardile</b></li><li><b>Compared: - Dr. Deepak Bhosle.</b></li></ul>
6.	<b>Speakers/ Judges/ Chairman/ Panel Team – Brief introduction with their achievements.</b>
	<b>Speakers :</b> <ul style="list-style-type: none"><li>• <b>Dr. Deepak Bhosle (HOD Pharmacology, MGM Medical College, Aurangabad)</b></li><li>• <b>Bhagyashree Shevade (Assistant Project Manager, Diagnosearch CRO)</b></li><li>• <b>Devyani (Unblinded-Clinical Research Associate, Diagnosearch CRO)</b></li><li>• <b>Akash Autade (Blinded-Clinical Research Associate, Diagnosearch CRO)</b></li></ul>
7.	<b>Participants &amp; Delegates – No of participants &amp; delegates/ teams with their names.</b>
	<b>All Study staff</b>
8.	<b>Prize Distribution etc – Brief Summary of the Proceeding</b>





**MAHATMA GANDHI MISSION MEDICAL COLLEGE & HOSPITAL ,  
AURANGABAD**

**Academic Event Report**

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**Professor & Head**  
**Pharmacology Department**  
**MGM Medical College & Hospital, Aurangabad**



shaikh yahiya Ali <yahiya.mgmmcha@gmail.com>

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## SII-rBCG/COVID-19/IN-02- SIV- 11 May- SIV presentations

1 message

10 May 2020 at 14:23

**Bhagyashree Shevade** <bhagyashree.shevade@diagnosearch.com>  
To: "drtayadeps@gmail.com" <drtayadeps@gmail.com>  
Cc: "drdeepakbhosle@gmail.com" <drdeepakbhosle@gmail.com>, shaikh yahiya Ali <yahiya.mgmmcha@gmail.com>, "drshraddha.mgmmcha" <drshraddha.mgmmcha@gmail.com>


Dear Team,

Attached are the SIV ppts. for your reference.

Regards,

Bhagyashree

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 SII-rBCG-COVID-19-IN-01\_SIV Presentations.zip  
3800K





**MAHATMA GANDHI MISSION MEDICAL COLLEGE & HOSPITAL ,  
AURANGABAD**

**Academic Event Report**

Conferences/ Seminars/ CME/Workshop/ Quiz/ Debate/ Guest Lecture etc.

Date:- 29-jun-2020

No.	Event Report
1.	<b>Name &amp; Level of Event – College/ Regional/ State/ National/ International.</b>  <b>Site Initiation Visit , –Workshop, National level.</b>
2.	<b>Background/ Introduction – Need/ reasons for holding the prg, Name of Association/ Collaboration etc.</b> “A randomized open-label study to evaluate the efficacy and safety of favipiravir and umifenovir as compared to favipiravir alone in moderate hospitalized adult Indian COVID-19 patients.”
3.	<b>Venue -</b>  • <b>Pharmacology Department , MGM Medical college AURANGABAD</b>
4.	<b>Sponsors – Glenmark</b>  <b>Glenmark SMO</b>
5.	<b>Inauguration – including the details of Chief Guest, Guest(s) of Honor, gist of speeches given, compared by etc.....</b>  • <b>CHIEF GUEST: - Dr.Anand Nikalje</b> <b>Compared: - Dr. Deepak Bhosle.</b>
6.	<b>Speakers/ Judges/ Chairman/ Panel Team – Brief introduction with their achievements.</b>  <b>Speakers :</b> • <b>Vishakha Utekar (Clinical Research Associate, Glenmark)</b>
7.	<b>Participants &amp; Delegates – No of participants &amp; delegates/ teams with their names.</b>  <b>All Study staff</b>
8.	<b>Prize Distribution etc – Brief Summary of the Proceeding</b>





**MAHATMA GANDHI MISSION MEDICAL COLLEGE & HOSPITAL ,  
AURANGABAD**

**Academic Event Report**

Conferences/ Seminars/ CME/Workshop/ Quiz/ Debate/ Guest Lecture etc.

**9.** **Valedictory Ceremony** – *Brief of the proceedings including chief guest etc and who conducted it.*

**10.** **Highlights of the Event** – *Brief about the main highlight(s) of the event.*

- Site Staff, Facilities and Study Supplies
- Compliance to Protocol/Amendment(s) and regulatory requirements
- Subject Recruitment & Enrollment
- Informed Consent Procedures/Process
- Case Report Form (CRF) / Electronic Case Report Form (eCRF) Requirements
- Data Entry and Query Resolution Timelines
- Monitoring Procedures
- IP storage and accountability
- Laboratory Procedures and Biological Samples
- Essential Documents and ISF review

**Professor & Head**

**Pharmacology Department**

**MGM Medical College & Hospital, Aurangabad**





## Study Site Team Responsibility List

Protocol No.:	GPL/CT/2020/004/III	Sponsor:	Glenmark Pharmaceuticals Ltd., India
Site No.:	06	Investigator:	Dr. Anand Nikalje

Name of the site team member	Role in the Study	Full Signature	Abbreviated signature	* Study Responsibilities	Start Date	Investigator signature with date	End Date	Investigator signature with date
Dr. Anand Nikalje	PI			1-23	29 June 2020			
Dr. Syed Umar Quadri	CO-I			2-23	29 June 2020			
Dr. Rohan Gundre	CO-I			2-23	29 June 2020			
Dr. Babhanaji Adkine	CO-I			2-23	29 June 2020			
Dr. Prashant Akulwar	CO-I			2-23	29 June 2020			
Dr. Pradeep Tawle	CO-I			2-23	29 June 2020			
Dr. Nilofar Shaikh Patel	CO-I			2-23	29 June 2020			
Dr. Rohit Jacob	CO-I			2-23	29 June 2020			

This form should be initiated at the Site Initiation visit.

Add rows if required

§: Original should remain at site until site closure



## Study Site Team Responsibility List

Protocol No.:	GPL/CI/2020/004/III	Sponsor:	Glenmark Pharmaceuticals Ltd., India
Site No.:	06	Investigator:	Dr. Anand Nikalje

Name of the site team member	Role in the Study	Full Signature	Abbreviated signature	* Study Responsibilities	StartDate	Investigator signature with date	End Date	Investigator signature with date
Soni Agale	Primary coordinator		soni	2, 4, 6, 7, 9, 11, 12, 15, 18, 19, 22	29 June 2020	 29/6/2020		
Archana Sawsakke	Study coordinator		AS	2, 4, 6, 7, 9, 11, 12, 15, 18, 19, 22	29 June 2020	 29/6/2020		
Yogesh Tak	Study Co coordinator		Y	2, 4, 6, 7, 9, 11, 12, 15, 18, 19, 22	17 Jul 2020	 17/7/2020		

Anand Nikalje  
17/7/2020

This form should be initiated at the Site Initiation visit.

Add rows if required

§: Original should remain at site until site closure





MAHATMA GANDHI MISSION MEDICAL COLLEGE & HOSPITAL,  
AURANGABAD

### Academic Event Report

Conferences/ Seminars/ CME/Workshop/ Quiz/ Debate/ Guest Lecture etc.

Date:- 11-07-2020

No.	Event Report
1.	Name & Level of Event – <i>National</i>
	<b>Site Initiation Visit , –Workshop, National level.</b>
2.	Background/ Introduction – <i>Need/ reasons for holding the prg, Name of Association/ Collaboration etc.</i>
	Protocol Number:- COVID 19/AYUSH-ICMR 2020/Adjunct Protocol-AF-III Version: 3.5-F, Dated 11 <sup>th</sup> June 2020 Title:- :“A Randomized, Open Label, Parallel Efficacy, Active Control, Multi- Centre Exploratory Drug Trial to Evaluate Efficacy and Safety of an Ayurvedic Formulation III [Yashtimadhu] as Adjunct Treatment to Standard of Care for the management of Mild to Moderate COVID-19 Patients”.
3.	Venue -
	<ul style="list-style-type: none"><li>• Pharmacology Department , MGM Medical college AURANGABAD</li></ul>
4.	Sponsors – <i>Name &amp; details If any</i>
	CSIR IIIM JAMMU
5.	Inauguration – <i>including the details of Chief Guest, Guest(s) of Honor, gist of speeches given, compared by etc.....</i>
	<ul style="list-style-type: none"><li>• CHIEF GUEST: -</li><li>• Dr Syed Umar Quadri, Dr Sunil Dorle, Dr Rohit Jacob</li></ul> Compared: - Dr. Deepak Bhosle.
6.	Speakers/ Judges/ Chairman/ Panel Team – <i>Brief introduction with their achievements.</i>
	Speaker: <ul style="list-style-type: none"><li>• Mr.Aditya Nimbalkar (Clinical Research Associate, Ardent Clinical Research Services)</li><li>• Mrs.Pranjal Ausekar (Project Manager, Ardent Clinical Research Services)</li><li>• Dr.Deepak Bhosle-Professor &amp; Head,Pharmacology Department</li><li>• Dr Syed Umar Quadri-Associate Prof. Dep. of Medicine</li></ul>
7.	Participants & Delegates – <i>No of participants &amp; delegates/ teams with their names.</i>
	All Study staff
8.	Prize Distribution etc – <i>Brief Summary of the Proceeding</i>





**MAHATMA GANDHI MISSION MEDICAL COLLEGE & HOSPITAL ,  
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- Compliance to Protocol/Amendment(s) and regulatory requirements
- Subject Recruitment & Enrolment
- Informed Consent Procedures/Process
- Good documentation practice
- New drug and clinical trial rules 2019 guidelines
- ICH-GCP Guidelines
- Case Report Form (CRF)
- Monitoring Procedures
- Central and local laboratory procedures
- Essential Documents and ISF review.
- Discussion on IP management review & accountability ,IMP storage requirement

**Professor & Head  
Pharmacology Department  
MGM Medical College & Hospital, Aurangabad**





MAHATMA GANDHI MISSION MEDICAL COLLEGE & HOSPITAL,  
AURANGABAD

### Academic Event Report

Conferences/ Seminars/ CME/Workshop/ Quiz/ Debate/ Guest Lecture etc.

Date:- 11-07-2020

No.	Event Report
1.	<b>Name &amp; Level of Event – National</b>  <b>Site Initiation Visit , –Workshop, National level.</b>
2.	<b>Background/ Introduction – Need/ reasons for holding the prg, Name of Association/ Collaboration etc.</b>  Protocol Number:- Covid-19/RARD/2020 Title:- "A Randomized, Open Label, Single Centre, Observational, Prospective, Clinical Study to Evaluate the Efficacy and Safety of GanjhuVir syrup and tablet when administered along with Standard of Care (SOC) and compared against SOC inCovid-19 positive patients."
3.	<b>Venue -</b>  • Pharmacology Department , MGM Medical college AURANGABAD
4.	<b>Sponsors – Name &amp; details If any</b>  Radhika Ayurveda Research and Development.
5.	<b>Inauguration – including the details of Chief Guest, Guest(s) of Honor, gist of speeches given, compared by etc.....</b>  • CHIEF GUEST: - • Dr Syed Umar Quadri, Dr Prashant Mahajan Compared: - Dr. Deepak Bhosle.
6.	<b>Speakers/ Judges/ Chairman/ Panel Team – Brief introduction with their achievements.</b>  <b>Speaker:</b> <ul style="list-style-type: none"><li>• Mr.Aditya Nimbalkar (Clinical Research Associate, Ardent Clinical Research Services)</li><li>• Mrs.Pranjal Ausekar (Project Manager, Ardent Clinical Research Services)</li><li>• Dr.Deepak Bhosle-Professor &amp; Head,Pharmacology Department</li><li>• Dr Syed Umar Quadri-Associate Prof. Dep. of Medicine</li></ul>
7.	<b>Participants &amp; Delegates – No of participants &amp; delegates/ teams with their names.</b>  All Study staff
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**MAHATMA GANDHI MISSION MEDICAL COLLEGE & HOSPITAL ,  
AURANGABAD**

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- Essential Documents and ISF review.
- Discussion on IP management review & accountability ,IMP storage requirement

*banu*

**Professor & Head  
Pharmacology Department  
MGM Medical College & Hospital, Aurangabad**





## MGM INSTITUTE OF HEALTH SCIENCES

(Deemed University u/s 3 of UGC Act, 1956)

Grade 'A' Accredited by NAAC

### MGM SCHOOL OF PHYSIOTHERAPY

Sector-1, Kamothe, Navi Mumbai – 410209

- Mrs. Preeti Athavale, Assistant Professor, Department of Biomedical Engineering, MGM Engineering college focused her talk on the steps required in order to take an idea from the stage of concept formation all the way upto prototype
- Dr. Jennifer V D'souza, Assistant Professor, MGM School of Physiotherapy spoke about the need and opportunities that are available for innovation in rehabilitation. She sensitized the students to the already existing technologies and their limitations and pressed on the need to work in furthering innovation in various sectors of rehabilitation



**Fig 2: Talk on identifying a clinical problem by Dr. Jennifer D'souza (PT)**

- Dr. Juhi Bharnuke (PT) presented an e-tour of Atal Innovative Mission (AIM) scheme by NITI Aayog, Government of India for financial aid provided to start-ups through tinkering labs, incubation centers and funding support to small and medium scale industries.
- Dr. Arunkumar Lokandhe, Professor, Department of Biochemical Engineering, MGM Engineering college shared his story of success where he was able to recycle waste paper accumulated at institution's and hospital level and how he was able to convert the waste paper into recyclable paper which could be used for various purposes.



## **MGM INSTITUTE OF HEALTH SCIENCES**

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## **MGM SCHOOL OF PHYSIOTHERAPY**

Sector-1, Kamothe, Navi Mumbai – 410209



**Fig 3: Attendees of Workshop**

- The session concluded with vote of thanks to students, speakers and organizers.





**Institution's Innovation Council**  
MGM Institute of Health Sciences, Navi Mumbai  
**One day workshop on: “*Shaping of Ideas for Innovation*”**  
Organised by MGM School of Physiotherapy,  
MGMIHS, Kamothe, Navi Mumbai  
**On 10<sup>th</sup> October, 2019 (Thursday, 1:00pm to 4:00pm)**

**Programme Schedule**

<b>Time</b>	<b>Topic</b>	<b>Speakers</b>
1.00p.m. -1.15p.m.	Opening Remarks: Sensitize students to Innovation	Dr. Rajani Mullerpatan Professor-Director, MGM School of Physiotherapy, Navi Mumbai
1.15 p.m. – 1.30p.m.	Identifying Opportunities for Innovation in Rehabilitation	Dr. Jennifer V D'souza (PT), Assistant Professor, MGM School of Physiotherapy, Navi Mumbai
1.30 p.m. - 1.00 p.m.	E-tour of Atal Innovation Mission (AIM) website	Dr. Juhi Bharnuke (PT), Assistant Professor, MGM School of Physiotherapy, Navi Mumbai
2.00 p.m. - 2.15 p.m.	Process of Biomedical Device Innovation: a step by step approach	Mrs. Preeti Athavale, Assistant Professor, MGM Department of Biomedical Engineering
2.15 p.m.- 2.30 p.m.	Making of Recyclable Pen: Success Story	Miss. Palak Trivedi and Miss. Manasi Desai (II BPT Students)
2.30 p.m. - 3.00 p.m.	Documentary: “The Art of Innovation”	
3.00 p.m. -3.20 p.m.	Effective Recycling of Paper waste	Dr. Arunkumar Lokhande, Professor, Chemical Engineering Department, MGM College of Engineering and Technology
3.20 p.m. - 3.35 p.m.	How Health Professionals can partner with Engineers?	Interactive session between faculty and students
3.35 p.m. – 4.00 p.m.	Valedictory and Vote of thanks	Dr. Juhi Bharnuke (PT)



## EVENT

**Idea mapping for Entrepreneurship by  
Dr. Mala Parab, Associate Prof, D.Y.Patil college**

**AT**

**MGMSBS Navi Mumbai**

**ON**

**27th September 2019**

**TOTAL PARTICIPANTS**

**MSc students of MGMSBS**

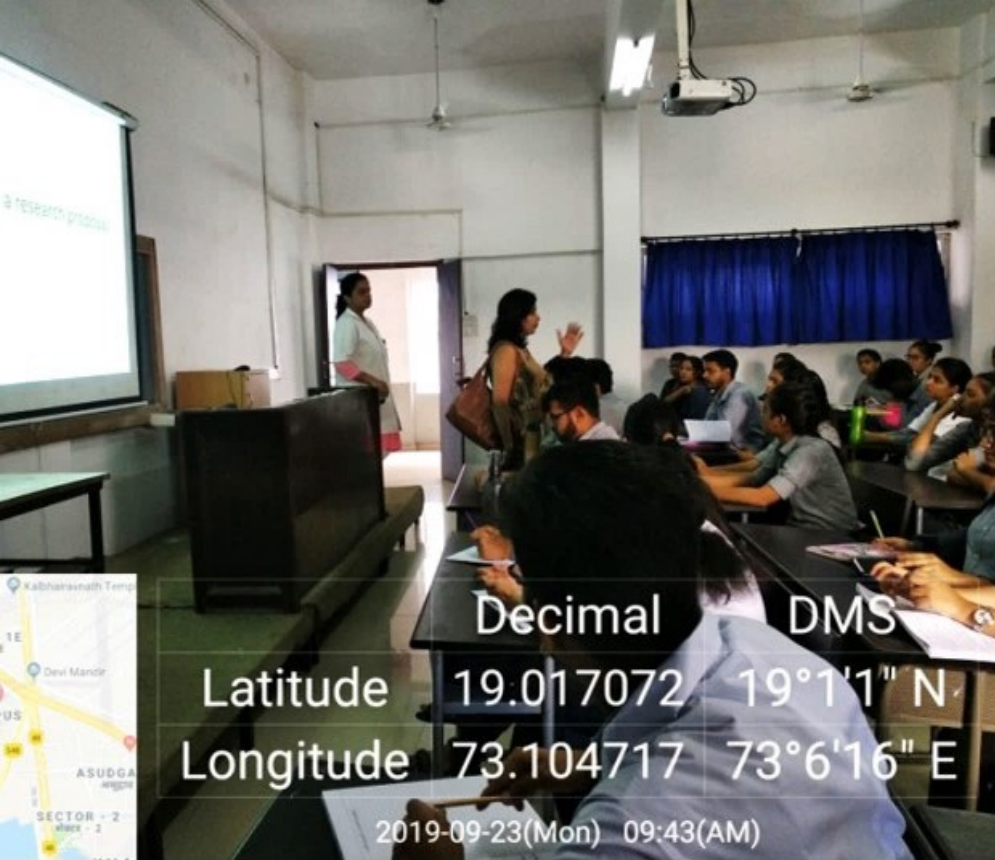


# Lecture by Dr. Vinay Mallik



BS arranged a lecture for all PG students on "**Research Publication & Citation**" on 14th August 2019 conducted by **Dr. Vinay Mallik**, Ph.D. Scientist, Coordinator, DBT Star College and DST - FIST Schemes, Assistant Professor, Department of Biotechnology, Modern College, Pune





Decimal DMS

Latitude 19.017072 19°1'1" N  
Longitude 73.104717 73°6'16" E

2019-09-23(Mon) 09:43(AM)



Decimal DMS

Latitude 19.017072 19°1'1" N  
Longitude 73.104717 73°6'16" E

2019-09-23(Mon) 09:42(AM)

**EVENT**

**Research Paper writing by Dr. Niharika Swai  
(Associate Prof - MGM Dental college)**

**AT**

**MGMSBS Navi Mumbai**

**ON**

**23rd September**

**TOTAL PARTICIPANTS**

**104 MSc students**





## MGM INSTITUTE OF HEALTH SCIENCES

(Deemed University u/s 3 of UGC Act, 1956)

Grade 'A' Accredited by NAAC

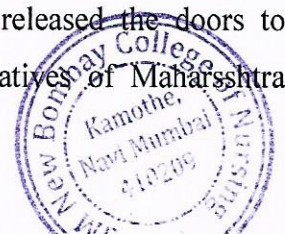
### MGM NEW BOMBAY COLLEGE OF NURSING

5<sup>th</sup> Floor, MGM Educational Campus, Plot No. 1 & 2, Sector-1

Kamothe, Navi Mumbai – 410 209

#### Report of Activity

Date	: 15 <sup>th</sup> October, 2019	Duration: 6 hours
Name of the activity	: One day Workshop on "Empowering Entrepreneurship Ecosystem"	
Organizing Institute	: Institutional Research Review Committee, MGMNBCON, Navi Mumbai	
Venue	: Auditorium, 3 <sup>rd</sup> floor, University Bldg. MGMIHS, Navi Mumbai	
Collaborating agency	: Incubation and Innovation Centre, MGMIHS, Navi Mumbai	
Name of the scheme	: Institutional's Innovation Council (IIC) MGMIHS, Navi Mumbai formulated under the guidance flagship of MHRD, GOI.	
No. of resource persons	: Total three (2 from outside and one in-house faculty)	
No. of Students Participated	: Total 232 participants. 220 ( including UG, PG students of Nursing and 20 students of Dept. of Molecular Biology Sciences, MGMIHS, Navi Mumbai) and 12 faculty of MGMNBCON.	
Brief of the Activity	: MGMNBCON has organized one day workshop under the guidance of Dr. Raman P. Yadav, Director, MGMIHS Incubation and Innovation Centre and Convener, Institutional's Innovation Council (IIC), MGMIHS as a part of continuation of IIC activities of first quarter and celebration of National Innovation Day on the birth anniversary of Dr. Abdul Kalam. The aim was to foster the culture of Innovation amongst students and faculties, to acquaint them with the journey of idea to innovations till entrepreneurship and to orient them with required attributes and support provided from IIC to transform the innovations in prototype/product. Details of activities performed during the workshop are attached for the reference. The sessions were informative to sensitize the participants about requirement of innovations and entrepreneurship in every field, including nursing for the benefits of the stakeholders by innovating cost effective methods of health delivery. Sessions boosted the confidence among the students and faculties that campus has system and facilitative environment for the same. Many examples of nurse entrepreneur and intrapreneur and their journey was highlighted which released the doors to inquisitiveness. The session enlightened the students on the various initiatives of Maharashtra Government to promote entrepreneurship.	



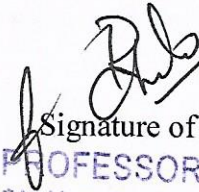
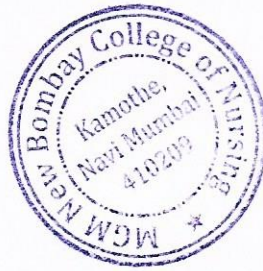
Annexure:

1. List of students participated : Yes
2. Photos : Yes
3. Programme schedule : Yes



Signature of Organizer

Date: 18/10/2019



Signature of Director

PROFESSOR & DIRECTOR  
MGM New Bombay College of Nursing  
Kamothe, Navi Mumbai - 410209





**Institution's Innovation Council,**  
MGMIHS, Navi Mumbai



One day workshop on  
“*Empowering Entrepreneurship Ecosystem*”

*Organized by*

**MGM New Bombay College of Nursing &  
MGMIHS Incubation and Innovation Centre,  
MGMIHS, Navi Mumbai**

*At Auditorium, MGMIHS, Kamothe, Navi Mumbai*  
On 15<sup>th</sup> October, 2019 (Tuesday, 10.00 am – 3.00 pm)

**With the objectives:**

- To foster culture of Innovation amongst students and faculties
- To acquaint them with the journey of idea to innovations till entrepreneurship
- To orient them with required attributes and support provided from IIC to transform the innovations in prototype/product

**Programme Schedule**

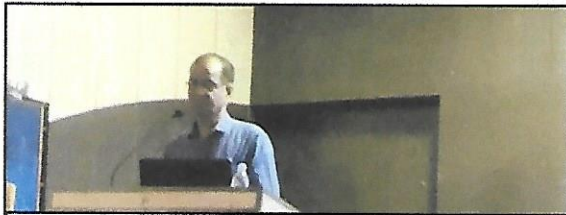
Time	Session / activity	Resource person
10.00 - 10.30 am	Inauguration ceremony	
	Welcome address	Mrs. Susan Jacob Professor, MGMNBCON
	Prayer Songs	II yr B.Sc. Nursing Students
	Lamp lighting	
	Address by Dignitary	Dr. Narshetty, Dean, MGM Medical College and Hospital  Dr. Raman Yadav, Convener, IIC MGMIHS, Navi Mumbai.
10.30 - 11.30 am	Role of MCED in development of Entrepreneurship	Ms. Deepa Raut, Sr. Faculty, MCED, Maharashtra
11.30 - 11.45 am	Tea Break	
11.45 - 12.45 pm	Nurse Entrepreneurship Global and National Scenario: Attributes and facilities required	Dr. Jyoti Chaudhari, Asso. Professor, MGMNBCON
12.45 - 1.30 pm	Refreshment	
01.30 - 2.30 pm	Innovations by Nurses: Not dream, but reality.	Ms. Sushila Samuel, Director, South East Asia Middle east, Arjo
02.30 - 3.00 pm	Concluding Remarks and Vote of thanks	Dr. R. Ponchitra, Professor and Vice Principal, MGMNBCON
	National Anthem	



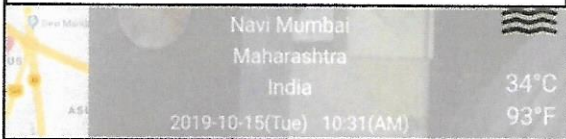


# Glimpses of one day workshop on "Empowering Entrepreneur Ecosystem"

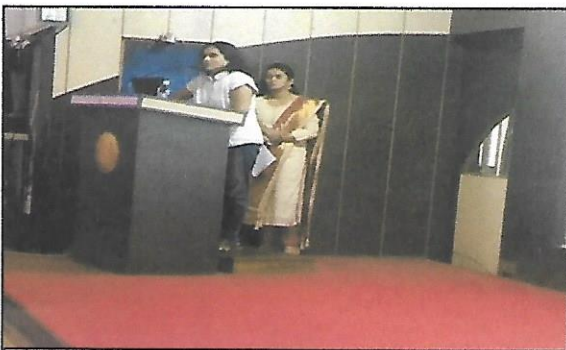
Organized by MGM New Bombay College of Nursing & MGMIHS Incubation and Innovation Centre, MGMIHS, Navi Mumbai on 15th October, 2019



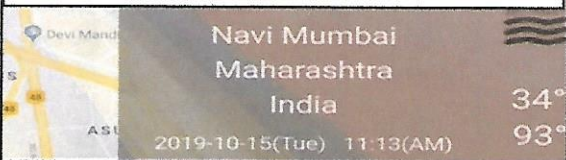
Address by Dr. Raman Yadav, Director of MGMIHS incubation and Innovation Centre



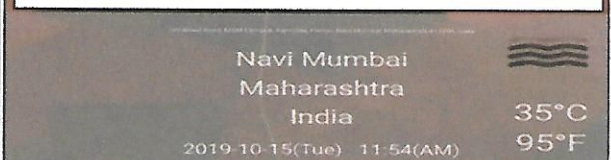
Address by Dr. Narshetty, Dean MGM Medical College and Hospital



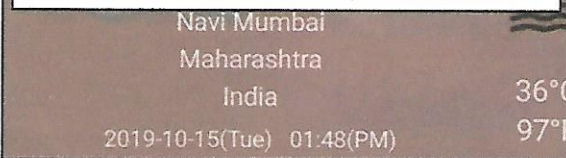
Session by Ms. Deepa Raut, Sr. Faculty, MCED, Maharashtra



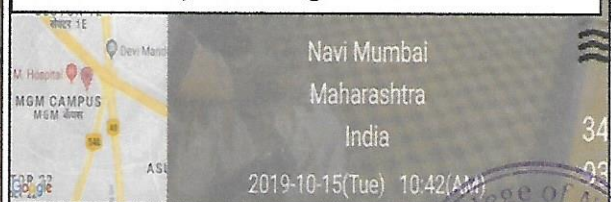
Session by Dr. Jyoti Chaudhari, Asso. Professor, MGMNBCON



Ms. Susan Jacob, Professor, MGMNBCON welcomed Ms. Sushila Samuel, Director, Arjo Health Care (ME &SEA) for the session



Audience engross during the sessions.





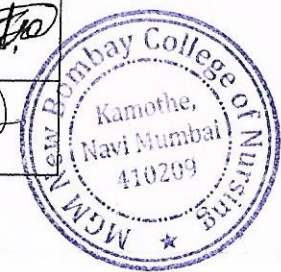
Total 232 (Pg 1 to 21)

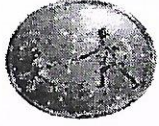


**Institution's Innovation Council**  
**MGM Institute of Health Sciences, Navi Mumbai**  
**Empowering Entrepreneurship Ecosystem**

Jointly Organised by MGM New Bombay College of Nursing and MGMIHS Incubation and Innovation Centre,  
 MGMIHS, Navi Mumbai  
 On 15<sup>th</sup> October, 2019 (Tuesday, 10:00am to 03:00pm)

<u>Sr. No</u>	<u>Name</u>	<u>Department</u>	<u>Email Id</u>	<u>Phone no.</u>	<u>sign</u>
1	D. Eabin aze	B.Sc Nursing	eabinazeedennis@gmail.com	7339653803	D. Eabin
2	ATHIRA PANICKER	BSC Nursing	athirapanicker007@gmail.com	8898063824	ATHIRA
3	PRATIKSHA BOBADE	BSC Nursing	bobadepratiksha89@gmail.com	8693039528	Pratiksha
4	BHARGAVI BORA	BSC Nursing	bhargavibora7@gmail.com 9167825159	9167825159	Bhargavi
5	Neha Singh	BSC Nursing	nehasingh5577@gmail.com	8879409634	Neha
6	Sanchita Gharat	BSC Nursing	Sanchitgharat9708@gmail.com	9833029708	S. Gharat
7	TWINKAL RATHOD	BSC NURSING	twinkalrathod@gmail.com	9715823899	TJR
8	Samiksha M. Mhatre	BSc Nursing	samiksha.mhatre30@gmail.com	9324216182	Mhatre
9	Binita Abraham	Bsc Nursing	binimolben134@gmail.com	9892537653	Binita





**Institution's Innovation Council**  
**MGM Institute of Health Sciences, Navi Mumbai**

**Empowering Entrepreneurship Ecosystem**

**Jointly Organised by MGM New Bombay College of Nursing and MGMIHS Incubation and Innovation Centre,  
MGMIHS, Navi Mumbai  
On 15<sup>th</sup> October, 2019 (Tuesday, 10:00am to 03:00pm)**

<u>Sr. No</u>	<u>Name</u>	<u>Department</u>	<u>Email Id</u>	<u>Phone no.</u>	<u>sign</u>
10)	Sayli Patil	B.sc Nsg		8779869232	
11)	Vedanta Pawde	B.sc Nsg.		7045609917	
12)	shweta Pandit	B.sc Nsg.		7066996891	
13)	Pooya Sharma	B.sc Nsg.		8459128351	
14)	shoabani nondal	B.sc Nsg.		7304194726	
15)	Kenaz Rajan	B.sc Nsg.		9833780899	
16)	leena Hedau	B.Sc Nsg		8291029776	
17)	Pisupati D	B.Sc Nsg.			
18)	Rutik Kotkar	B Sc Nsg			







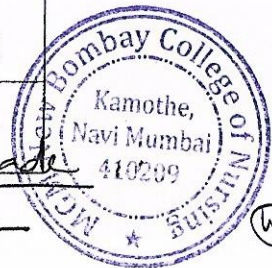
**Institution's Innovation Council**  
MGM Institute of Health Sciences, Navi Mumbai

**Empowering Entrepreneurship Ecosystem**

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MGMIHS, Navi Mumbai

On 15<sup>th</sup> October, 2019 (Tuesday, 10:00am to 03:00pm)

<u>Sr. No</u>	<u>Name</u>	<u>Department</u>	<u>Email Id</u>	<u>Phone no.</u>	<u>sign</u>
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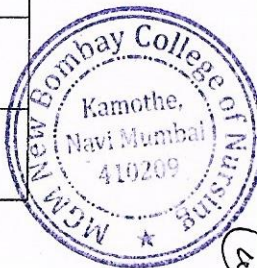
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<u>Sr. No</u>	<u>Name</u>	<u>Department</u>	<u>Email Id</u>	<u>Phone no.</u>	<u>sign</u>
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5.	Robinson Kuniakore.	Bsc. Nursing		8848064271	
6.	Mertina Mathew	B.Sc Nursing		7706756133	
7.	Lina Rachel Alex	B.Sc Nursing		9495137814	
8.	Priyansha Masih	B.Sc Nursing		7746830945	
9.	Pallavi Ladhar	Bsc Nursing		8779790041	



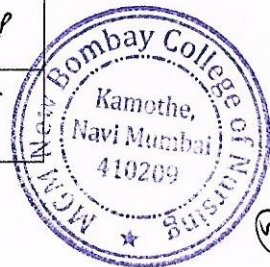




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<u>Sr. No</u>	<u>Name</u>	<u>Department</u>	<u>Email Id</u>	<u>Phone no.</u>	<u>sign</u>
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9.	Ansa Roy	BSc Nursing (1 <sup>st</sup> yr)	ansaroy2018@gmail.com	8928112882	





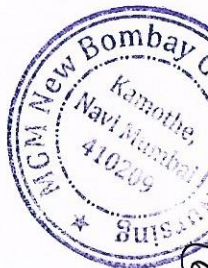


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1]	Rupali R. Gupta	MGMNBCON B.Sc Nursing	guptarupali2016@ gmail.com	9152466139	
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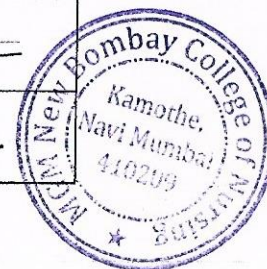
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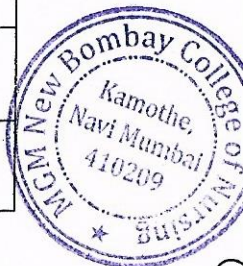
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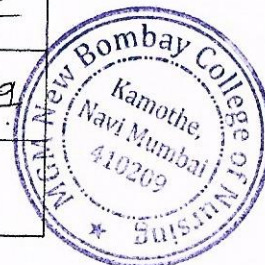




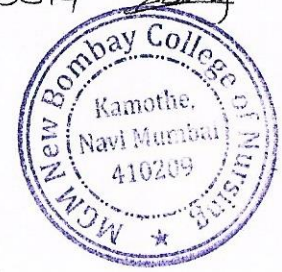
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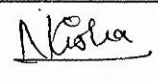

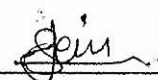


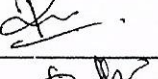
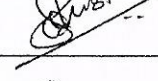
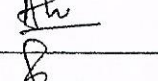
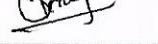


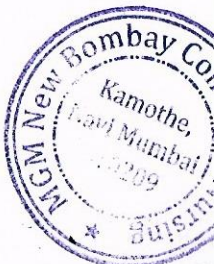
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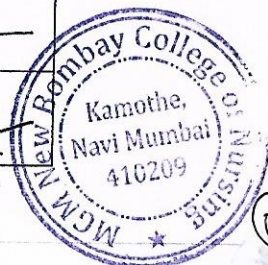
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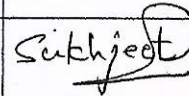
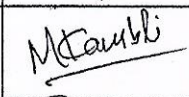
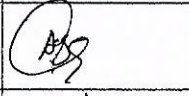
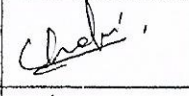

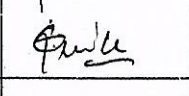
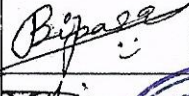




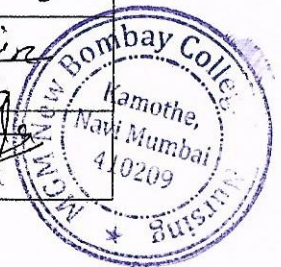
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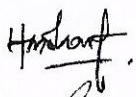
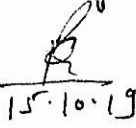
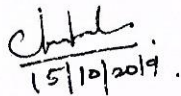
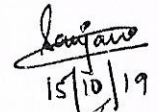

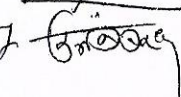
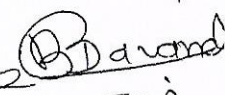
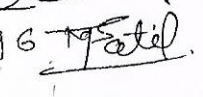
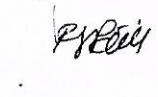
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MGMIHS, Navi Mumbai

On 15<sup>th</sup> October, 2019 (Tuesday, 10:00am to 03:00pm)

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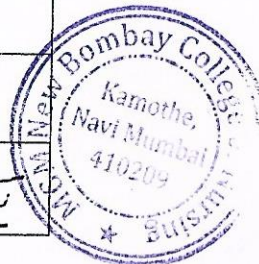
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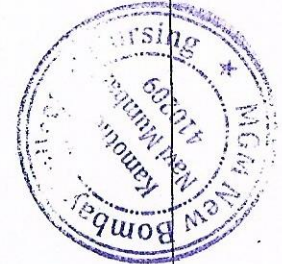
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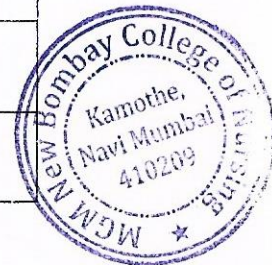
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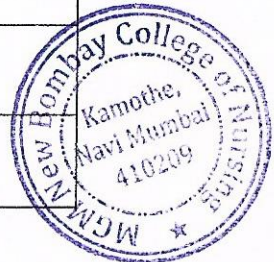




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# CONFERENCE REPORT

**NRSICON 2019**

**Nursing Research Society of India**



**23<sup>rd</sup> ANNUAL CONFERENCE**



On

*Systematic Review: A tool for evidence based practice*



*Organized by:*

**MGM NEW BOMBAY COLLEGE OF NURSING  
MGM INSTITUTE OF HEALTH SCIENCES**

(Deemed University u/s 3 of UGC Act, 1956)

**Grade 'A' Accredited by NAAC**

*On*

***28<sup>th</sup>, 29<sup>th</sup> & 30<sup>th</sup> November 2019***

**Venue:**

**University Auditorium, 3<sup>rd</sup> floor,  
MGM Institute of Health Sciences, Plot 1 & 2  
Sector - 1, Kamothe, Navi Mumbai – 410 206.**

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## **Background**

*Nursing Research Society of India* - The birth of NRSI in the year 1987 had been a very significant landmark in the history of nursing profession in India in general and nursing research in particular. The society, NRSI, the first of its kind in India, is a premier organization. The society was formed with the main aim of providing forum to nurse scientists by organizing conferences and workshops throughout the country to promote nursing research activities.

Today, with 1700 members including 35 international members on its roll, it has moved to the fore front of promoting research, disseminating the research findings, providing the best evidence for nursing practice and positively influencing the quality of nursing practice and nursing education in India. The society is growing steadily larger and stronger. NRSI promotes synergistic collaboration in the conduct, dissemination and utilization of nursing research.

**MGM New Bombay College of Nursing** is well known for its excellence in academic, co-curricular and extra-curricular activities in the country and strives hard to keep up the quality of education to provide globally competent nurses. It is one among the pioneering institutes in India, for successfully conducting the NPCC programme (recognized by Indian Nursing Council and Maharashtra Nursing Council) from the academic year 2017-18.

Systematic reviews integrate conscientious, explicit and judicious use of best evidences for exemplary decision making. A high quality systematic review is the most reliable source of evidence based practice generated from synthesized research findings.

In the health care sector systematic reviews provide highest level of evidence for quality patient care. Nurses in various sectors perform vital roles in assimilating evidences for providing quality health services to the mankind globally. Despite nurses conducting independent and interdisciplinary researches, the contribution on systematic review continues to reside in a luminal space.

Considering the demand of the hour the national conference “Systematic Review: A tool for evidence based practice” was organized on 28<sup>th</sup> & 29<sup>th</sup> November 2019 and the Post conference workshop on “Protocol preparation of Systematic Review” on 30<sup>th</sup> November by MGM New Bombay College of Nursing in collaboration with Nursing Research Society of India (NRSI).

## **Aim**

The aim of the National Conference was to introduce participants to various components of Systematic Review and familiarize them with different analysis software.

## **Objectives**

At the end of the conference, the participant will be able to;

- explain basics of evidence based health care
- describe stages of systematic review
- formulate research review question
- conduct relevant literature search
- assess the quality of evidence
- analyse and interpret the findings
- write a review report

## **Participants-**

The event brought together total 226 participants from various institutions across the country. The state wise distribution of participants were Maharashtra (14), Madhya Pradesh (15), Uttar Pradesh (2), Chhattisgarh (3), New Delhi (6), Gujarat (16), Assam (3), Tamil Nadu (3), Kerala (11), Dubai (1) and Nigeria (1). Among the participants there were 68 undergraduates, 71 post graduates, 13 PhD scholars and 74 faculties. The conference included 14 NRSI executive members, 2 members of Nursing honor society and nine resource persons from various reputed health institutions of India like, Sri Ramachandra Institute of Higher Education & Research (DU) Chennai, Q Med Knowledge Foundation Mumbai, Pondicherry Institute of Health sciences Pondicherry, MGM Institute of Health Sciences Mumbai, ACTREC Tata Memorial Center, Navi Mumbai, Kasturba Medical College, Mangalore.



# PROCEEDINGS

## Day One - 28/03/2019

The two days National conference on “**Systematic Review: A tool for evidence based practice.**” was held at MGM New Bombay College of Nursing (MGMNBCON), Kamothe On 28<sup>th</sup>, and 29<sup>th</sup> November 2019. The conference was inaugurated on 28<sup>th</sup> November 2019 at 9.30 am in the Auditorium of MGM Institute of Health Sciences (MGMIHS), Kamothe, Navi Mumbai. Dr. Shashank Dalvi, Hon. Vice Chancellor, MGMIHS, Dr. Silva Titus Chacko, President NRSI & Former Dean, CMC College of Nursing Vellore, and Dr. Anil Sharma, Secretary NRSI inaugurated the Conference and addressed the participants. Dr. R. Ponchitra, Professor & Vice Principal MGMNBCON and Organising Secretary welcomed the Guests of Honor. Dr. Prabha K. Dasila Professor & Director MGMNBCON and Organizing Chairperson unfolded the theme by emphasizing the increase in use of evidences from previously conducted studies and briefed about various activities planned for all the three days of the conference.



## WELCOME ADDRESS

The formal inaugural ceremony commenced with welcome address by Dr. R. Ponchitra, the Organising Secretary. She gave a brief introduction about the guests of honour Dr. Shashank Dalvi, Hon. Vice Chancellor, MGMIHS. She also elaborated on the history of MGMIHS and MGMNBCON. The dignitaries were felicitated with saplings. The inaugural lamp was lighted by the dignitaries which was followed by the address from Dr. Anil Sharma, Secretary NRSI. He introduced the NRSI, their achievements and the future plans. Dr. Shashank Dalvi addressed the gathering & appreciated the initiative for organizing the conference with the right theme at the right need of the hour.

Nursing honors Society “Hall of Fame 2019” was awarded to Dr. Usha Ukande, Former President NRSI. She was felicitated with a shield and Shawl by the Hon’ Vice Chancellor MGMIHS, President NRSI and Director MGMNBCON. The inaugural ceremony ended with the vote of thanks by Mrs. Preethi Maria Mathews, Associate Professor, MGM New Bombay College of Nursing, Kamothe.





## UNFOLDING THE THEME



The theme of the National conference on “**Systematic Review: A tool for evidence based practice.**” was unfolded by Dr. Prabha K. Dasila, Professor and Director, MGM New Bombay College of Nursing, Kamothe, Navi Mumbai.

She addressed the audience that today's health care environment is very complex and greatly different from the past. Over the period there is enormous explosion in technologies, methods of treatment, drugs and opportunities to disseminate knowledge, which places the health care professionals including nurses in a challenging position to keep themselves abreast with the new knowledge. The discovery of new knowledge provides the foundation for high-quality evidence-based practice.

She also mentioned that the researchers in nursing carryout work in nursing education, administration and patient care with an ultimate goal to develop a body of knowledge for the profession. Nowadays the researchers are increasingly using evidences from previously conducted studies to inform their own research question. These are considered as the gold standard for summarizing evidence found in research literature.

Considering the fact the organizing committee had extensive deliberations on various themes and subthemes and finally concluded to conduct NRSICON 2019 on **Theme - Systematic Review: A tool for Evidence Based Practice**

# NRSICON 2019

## *SYSTEMATIC REVIEW: A TOOL FOR EVIDENCE BASED PRACTICE*

### Programme Schedule

#### Conference: Day 1- 28<sup>th</sup> November 2019

Time	Session	Resource Person	Chairperson
8.00 am to 9.00 am	<b>Registration &amp; Break fast</b>		
9.00 am to 10.00 am	<b>Session 1. Introduction to systematic Review</b> <ul style="list-style-type: none"> <li>• What is Systemic Review &amp; its significance?</li> <li>• Types of Systematic Reviews</li> <li>• Systemic Review protocol &amp; Protocol Registries</li> </ul>	Dr. Silva Titus Chacko NRSI President	Dr. Prabha K. Dasila Professor & Director MGMNBCON, Navi Mumbai
10.00 am to 11.00 am	<b>Session 2. Steps to conduct Systemic Review</b> <ul style="list-style-type: none"> <li>• Formulating a systematic Review Question – PICOS, SPICE Frame work</li> </ul>	Dr. S. Venkatesan Senior Lecturer, Department of Bioinformatics, Sri Ramachandra Institute of Higher Edu. & Research [DU], Chennai.	Mrs. Lata Mandal, Jt Secretary NRSI
11.00 am to 11.30 am	<b>Inauguration</b>		
11.30 am to 11.45 am	<b>Tea break</b>		
11.45 am to 12.15 pm	<b>Session 3. Basics of Search Strategies</b> a. Search methods - Principles of searching, simple steps for conducting a Pub Med search; Advanced search in Pub Med for finding studies for systematic reviews	Dr. Vasumathi Sriganesh, Founder & Hon CEO, ‘Q’ Med Knowledge Foundation, Mumbai	Dr. Mary Mathews Professor & Principal MGM College of Nursing Navi Mumbai
12.15 pm to 1.00 pm	b. Different types of data bases - Some Key data bases, Hand searching and Citation indexes.		
1.00 pm to 2.00 pm	<b>Lunch</b>		
2.00 pm to 4.30 pm	<b>Session 4. Reference Management</b> <ul style="list-style-type: none"> <li>• Using a Reference Manager to Store all references, remove duplicates and use for Citations and Referencing.</li> </ul>		Mrs. Shanta De Jt. Editor NRSI
4.30 pm to 5.00 pm	<b>Tea</b>		
5.00 pm to 6.30 pm	<b>Concurrent paper &amp; Poster Presentation</b>		
6.30 pm onwards	<b>Entertainment &amp; Dinner</b>		



## Conference Day 2: 29<sup>th</sup> November 2019

Time	Session	Resource Person	Chairperson
8.00 am to 9.00 am	<b>Break fast</b>		
9.00 am to 10.00am	<b>Session 5: Data Extraction, synthesis &amp; Interpretation of results</b> <ul style="list-style-type: none"> <li>• Risk of bias &amp; Assessment of Risk of bias</li> <li>• Data synthesis 1. Narrative synthesis 2. Statistical synthesis</li> <li>• Identifying Heterogeneity</li> <li>• Calculation of Effect Size –Fixed Effect &amp; Random effect models</li> <li>• Statistical Vs Clinical Importance</li> </ul>	Dr. Aneesh Basheer, Professor of Internal Medicine , Vice Dean-Medical Education ,	Dr. Blessy Antony Treasurer, NRSI
10.00 am to 11.00 am	<b>Session 6: Meta-analysis</b> <ul style="list-style-type: none"> <li>• Use of Meta-analysis</li> <li>• Bias in meta-analysis</li> <li>• Sensitivity analysis</li> <li>• Forest Plots and interpretation</li> <li>• Funnel plots and interpretation</li> </ul>	Pondicherry Institute of Medical Sciences, Puducherry.	Dr. Suresh Sharma NRSI –Executive member
11.00 am to 11.15 am	<b>Tea Break</b>		
11.15 am to 12:30 pm	<b>Session 7: Reporting standards</b> PRISMA-E , QUOROM, EQUATOR, RAMESES, CONSORT	Dr. Maninder Singh Setia, Consultant Epidemiologist, MGMIHS, Mumbai	Dr. Jyoti Chaudhari Associate Professor MGMNBCON, Kamothe
12.30 pm to 01.15 pm	<b>GBM NRSI and Election for three post of Executives</b>	NRSI Membership and Returning officer	
1.15 pm to 2.00 pm	<b>Lunch</b>		
2.00 pm to 2.30 pm	<b>Nursing Honor Society Meeting</b>		
2.30 pm to 3.45 pm	<b>Session 8 :Statistical approaches and Software for Meta-analysis</b> <ul style="list-style-type: none"> <li>• Rev man</li> </ul>	Mrs. Sadhana Kannan, Biostatistician Department of Clinical Research Secretariat, ACTREC, Tata Memorial Center, Navi Mumbai	Dr. Usha Ukande Former NRSI President
3.45 pm to 4.40 pm	<b>Session 9: Implications for Evidence Based practice &amp; further research</b> <ul style="list-style-type: none"> <li>• Role of feasibility, appropriateness, meaningfulness, effectiveness</li> <li>• Factors to be considered when interpreting results in systematic Reviews.</li> </ul>	Dr. Assuma Beevi. T. M. Vice President, NRSI	Dr. Chanu Bhattacharya, Editor in chief NRSI Dr PVVF College of Nursing, Pad, Ahmednagar.
4.40 pm to 5.10 pm	<b>Valedictory</b>		
5.10 pm	<b>Tea</b>		

## Post Conference Workshop on Systematic Review

### Day 3rd- 30<sup>th</sup> November 2019

This workshop is designed to teach participants on how to plan, conduct and communicate the results of a Systematic Review. This will cover the basics of Evidence Generation including, identifying research priorities, refining the research question, protocol preparation and steps in carrying out Systematic Reviews. At the end of the workshop the participants will be able to:

1. Define evidence based health care, meta-analysis and Systematic Review
2. Formulate research question
3. Outline the steps while conducting Systematic Reviews
4. Data management in Systematic Reviews

Time	Topic	Resource Persons	
<b>08.50 am to 09.00 am</b>	Welcome Address		
<b>09.00 am to 09.15 am</b>	Introduction to Evidence Informed health care	Dr. B. Unnikrishnan,  Associate Dean & Professor of Community Medicine, Kasturba Medical College, Mangalore.	
<b>09.15 am – 09.45 am</b>	Identifying the Research Question and “PICO” development		
<b>09.45 am – 10:30 am</b>	Preparation of Protocol		
<b>Tea break – 10 minutes</b>			
<b>10:40 am – 11:40 am</b>	Search strategy + De-duplication		
<b>11:40 am – 12:10 pm</b>	Group work		
<b>12:10 pm – 01:00 pm</b>	Screening using Softwares + Group work		
<b>Lunch break – 45 minutes</b>			
<b>01:45 pm – 02:45 pm</b>	Assessing risk of bias + Group work		Dr. Prasanna Mithra P,  Associate Professor of Community Medicine, Kasturba Medical College, Mangalore.
<b>02:45 pm – 03:15 pm</b>	Data extraction		
<b>Tea break – 10 minutes</b>			
<b>03:25 pm – 03:55 pm</b>	Group work		
<b>03:55 pm – 04:30 pm</b>	Introduction to Meta – Analysis		
<b>04:30 pm – 05:00 pm</b>	Introduction to RevMan software and GRADE Pro		



## SCIENTIFIC SESSIONS: DAY 1 - 28.11.2019

### Session - 1

#### **Introduction to Systematic Review**

Dr. Silva Titus Chacko, President NRSI briefed about Systematic Review, difference between traditional reviews, types of systematic review and systematic review protocols and Registries.



### Session - 2

#### **Steps to conduct Systematic Review**

Dr. S. Venkatesan, Senior Lecturer, Department of Bio informatics, Sri Ramachandra Institute of Higher Edu. & Research [DU], Chennai. He elaborated on framing research questions with PICO, SPICE.



### Session - 3 & 4

#### **Basics of search strategies & Reference Management**

Dr. Vasumathi Sriganesh Founder & Hon CEO, Q Med Knowledge Foundation, Mumbai. She focused on mapping resources to needs, fundamentals of searching, Principles of searching, search methods, Boolean operators, MESH terms, PUB MED advanced search, Key databases, Hand searching & citation Indexes, Mendeley Reference manager .



## DAY 2 -29.11.2019

### Session - 5 & 6

#### **Data Extraction, Synthesis, Interpretation & Meta Analysis**

Dr. Aneesh Basheer, Professor of Internal Medicine, Vice Dean, Medical Education, Pondicherry Institute of Medical Sciences. He discussed on Meta-analysis in systematic reviews, effect measures, Bias in RCT and assessing the Risk of Bias, synthesizing the results of included studies, Meta-analysis and its nuances. He made the session interactive with hands on exercises



### Session - 7

#### **Reporting Standards**

Dr. Maninder Singh Setia, consultant, Epidemiologist, MGMIHS, Mumbai. He briefed the delegates on PRISMA statement & checklist, MOOSE, PROSPERO



### Session - 8

#### **Statistical Approaches and Software for Meta-Analysis**

Mrs. Sadhana Kannan, Biostatistician, Department of Clinical research Secretariat, ACTREC, Tata Memorial Centre, Navi Mumbai demonstrated on Live soft wares for meta analysis.





## Session - 9

### Implications For Evidence Based Practice & Future Research

Dr. Assuma Beevi. T, Vice President, NRSI discussed on Implications of EBP and further research, challenges for moving EBP forward, Role of feasibility, appropriateness, meaningfulness, effectiveness, factors to be considered when interpreting results in systematic reviews.



### NRSI GENERAL BODY MEETING

NRSI General Body meeting was conducted and the names of three elected executive members were announced. NRSI Post Doctoral fellowship was awarded to Dr. Suresh Sharma and Dr. Sivabalan. The invocation and Oath taking ceremony of newly registered members of Nursing Honor society was conducted.



## DAY 3 -29.11.2019

The post conference workshop on Systematic review was conducted by Dr. B. Unnikrishnan, Associate Dean, Professor of Community medicine, and Dr. Prasanna Mithra P, Associate Professor of Community medicine Kasturba Medical College, Mangalore on the third day of the conference.

The workshop consisted of hands on sessions on identifying research questions, searching literature reviews, de-duplicating the literatures, screening using software, assessing risk of bias and data extraction.

Introduction to Rev man Software was also done and hands on exercise using Rev-man Software was demonstrated.





## PAPER & POSTER PRESENTATION



Posters were presented on the topics related to the theme of the conference. Twenty six papers and fifteen posters were presented on 28/11/2019. Dr. Selva Titus Chacko, Dr. H.C. Rawat, Dr. Suresh Sharma and Sr. Doris evaluated the paper presentations. Dr. Nancy Fernandes and Dr. Blessy Antony evaluated the posters based on preset criteria. **Three best papers and posters were awarded.**

## POSTER PRESENTATION PRIZE DISTRIBUTION

The prize winners for the poster presentation competition was awarded with certificate



**Ms. Persis Gracy Philip**  
Second Year M.Sc Student, MGMNBCON  
**1<sup>st</sup> Prize**



**M V Smitha,**  
Reader, College of nursing, All India Institute of  
Medical Science, Bhubaneswar, Odisha  
**2<sup>nd</sup> Prize**



**Ms. Arathi Chandran**  
Second Year M.Sc Student, MGMNBCON  
**3<sup>rd</sup> Prize.**



## PAPER PRESENTATION PRIZE DISTRIBUTION

The prize winners for the paper presentation competition was awarded with certificate



**Prof. Dr. S. J. Nalini,**  
Principal, Faculty of Nursing  
Shri Ramachandra Institute of Higher  
Education and Research (DU) Tamil Nadu  
**1<sup>st</sup> Prize**



**Dr. Swapna Jose,**  
Professor, College of Nursing  
Thalassery, Kerala  
**2<sup>nd</sup> Prize**



Ms. Salina S, PhD. Scholar  
**3<sup>rd</sup> Prize.**



Mr. Sunil Joshi, Quality Nurse Manager,  
H M Patel Centre for Medical Care and  
Education and Shree Krishna Hospital,  
Gokal Nagar. **3<sup>rd</sup> Prize**

# CULTURAL ACTIVITIES





## VALEDICTORY FUNCTION

### Proceeding Report and Vote of Thanks



Dr. Ponchitra R. Professor & Vice Principal, Organising Secretary read out the report of the 2 days National Conference. She gave in depth detailing of the sessions carried out on 28<sup>th</sup> & 29<sup>th</sup> November 2019.

The session concluded with a valedictory function and a vote of thanks proposed by Mrs. Sarika Nair, Faculty, MGM New Bombay College of Nursing.



## FEEDBACK ABOUT THE CONFERENCE



The feedback about the National Conference was delivered by the representatives from the participants, NRSI Secretary and the Organizing Chairperson. The analysis of the feedback submitted by all the participants is as follows.

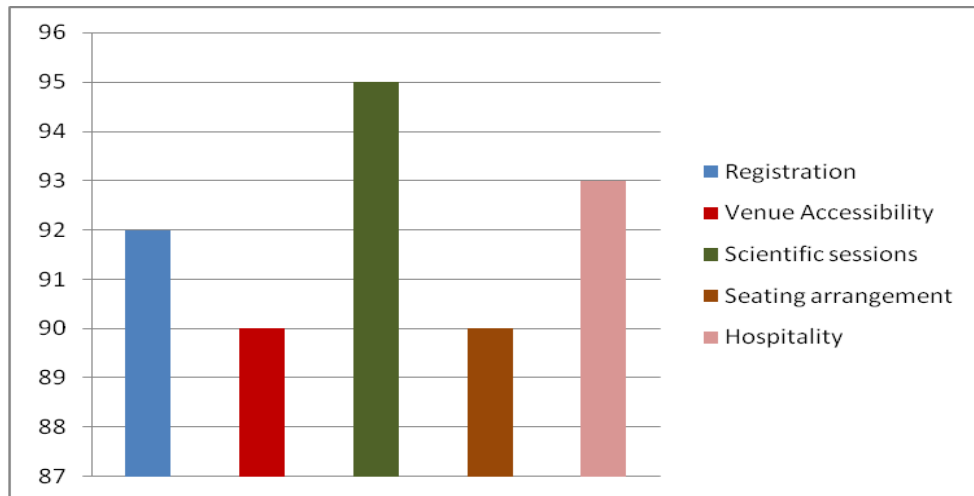


# FEEDBACK ANALYSIS

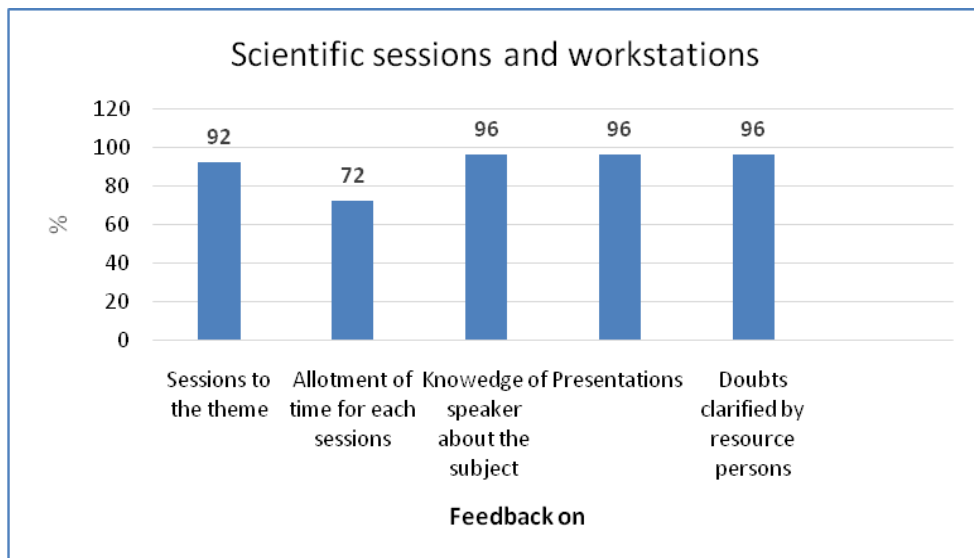
The conference was attended by **226** delegates. Feedback was obtained on overall organization and quality of the sessions

The feedback was obtained on 5 point Likert scale, with highest score (5) indicating as excellent and lowest score (1) poor quality.

## 1. Feedback on overall quality of Conference



## 2. Feedback on Scientific



### Sessions and workstations

All participants provided positive feedback with regard to overall scientific sessions of the conference. The feedback analysis on quality of overall sessions and workstation denotes that majority (96%) had responded that resource persons had enough knowledge, presentations were effective and their doubts were certified.

All participants provided positive feedback with regard to overall scientific sessions of the workshop.

<b>Scientific Sessions</b>	<b>Mean score (Max. Score 5)</b>	<b>Score in %</b>
Introduction to systematic Review	4.6	92
Steps to conduct Systemic Review	4.8	96
Basics of Search Strategies	4.3	86
Reference Management	4.4	88
Approach for Data Extraction	4.0	80
Data synthesis & Interpretation of results	4.4	88
Meta-analysis	4.6	92
Reporting standards	4.4	88
Statistical approaches and software for Meta-analysis	4.4	88
Implications for Evidence Based practice & further research	4.4	88

The overall session-wise feedback was found to be  $\geq 89\%$ .

**Conclusion:** The Conference had been an excellent source of information for all the participants especially post graduate students. The sessions were highly appreciated.









## MGM INSTITUTE OF HEALTH SCIENCES

(Deemed to be University)

Grade 'A' Accredited by NAAC

### MGM NEW BOMBAY COLLEGE OF NURSING

5<sup>th</sup> Floor, MGM Educational Campus, Plot No. 1& 2, Sector-1

Kamothe, Navi Mumbai – 410 209

#### Report of Activity

<b>Date</b>	: 8 <sup>th</sup> March 2020	Duration: 1 hr.
<b>Name of the activity</b>	: Mentoring session on 'Ideas and its diverse application'	
<b>Organizing Institute</b>	: Institutional Research Review Committee, MGMNBCON, Navi Mumbai.	
<b>Venue</b>	: Seminar hall, 2 <sup>nd</sup> floor, MGM hospital building, Kamothe Navi Mumbai.	
<b>Collaborating agency</b>	: Self-driven	
<b>Name of the scheme</b>	: Institutional Innovation Council (IIC) MGMIHS, Navi Mumbai. formulated under the guidance flagship of MHRD, GOI.	
<b>No. of resource persons</b>	: One. Dr. Jyoti M. Chaudhari, Asso. Professor, MGMNBCON	
<b>No. of Students Participated</b>	: Total 188 participants- 16 faculty and 172 UG, PG nursing students)	

**Brief of the Activity:** MGMNBCON has organized session for nursing students and faculty as a self-driven activity, a part of continuation of MGMIHS IIC activities of third quarter. The aim was to mentor the participants on multiple applications of one idea. Dr. Jyoti Chaudhari conducted session for the same. She explained various ideas, innovations and technology already existing (virtual atmosphere, mobile and various apps, voice technology, Artificial intelligence) and few are still in nut shell such as finding new sources of water, use of plastic for making reusable dresses, does not require frequent washing). Mentor gave examples of ideas for its applications in health, education, advocacy, sexual harassment, food security and workforce creation. On the occasion of upcoming International Women's Day 2020, Dr. Jyoti Chaudhari requested the participants to work on the ideas fostering women empowerment.

At the end of the session Dr. Prabha K. Dasila, Director, MGMNBCON felicitated Dr. Jyoti Chaudhari with sapling and certificate. Ms. Persis, 2<sup>nd</sup> year Msc. Nursing student thanked Dr. Jyoti Chaudhari on behalf of students.

#### Annexure:

1. List of participants : Yes ( Attendance sheet attached )
2. Photos : Yes
3. Programme schedule : Yes

Signature of Organizer



Signature of Director  
PROFESSOR & DIRECTOR  
MGM New Bombay College of Nursing  
Kamothe, Navi Mumbai - 410209





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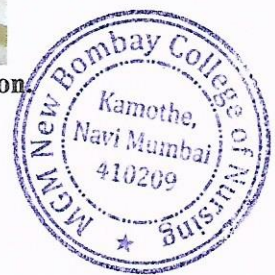
**Glimpses of mentoring session on "ideas and its diverse application" on 06.03.2020**



**Mentoring Session by Dr. Jyoti Chaudhari on Idea and its diverse application**



**Dr. Prabha K. Dasila felicitating Dr. Jyoti M. Chaudhari after the session.**





**Institution's Innovation Council,  
MGMIHS, Navi Mumbai**

3<sup>rd</sup> quarterly activity



*Organized by*  
**MGM New Bombay College of Nursing  
MGMIHS, Navi Mumbai**

*At Seminar Hall, 2<sup>nd</sup> Floor, MGM Hospital, Kamothe, Navi Mumbai  
On 6<sup>th</sup> March, 2020 (Friday, 2.30 pm – 3.30 pm)*

**Programme Schedule**

<b>Time</b>	<b>Session / activity</b>	<b>Resource person</b>
2.30 - 2.35 pm	Welcome	Ms. Persis, 2 <sup>nd</sup> year MSc. Nursing Student
2.35 - 3.25 pm	Mentoring session: Idea and its Diverse application	Dr. Jyoti Chaudhari, Asso. Professor, MGMNBCON
3.25 - 3.30 pm	Felicitation of Mentor and concluding remark	Dr. Prabha K. Dasila, Director, MGMNBCON







**Institution's Innovation Council,**  
MGMIHS, Navi Mumbai

3<sup>rd</sup> quarterly activity self-driven activity



Mentoring Session on  
**Ideas and its diverse application**

*Felicitations of Mentor*

**Dr. Prabha K. Dasila,**

Professor & Director, MGM New Bombay College of Nursing,  
Kamothe, Navi Mumbai.

*Mentoring Session*

**Dr. Jyoti M. Chaudhari,**

Associate Professor, MGM New Bombay College of Nursing,  
Kamothe, Navi Mumbai.

*Welcome by*

**Ms. Persis,**

2<sup>nd</sup> year M.Sc Nursing Student, MGM New Bombay College of  
Nursing, Kamothe, Navi Mumbai.

*Organized by*

**MGM New Bombay College of Nursing**

**MGMIHS, Navi Mumbai**

*At Seminar Hall, 2<sup>nd</sup> Floor, MGM Hospital, Kamothe, Navi Mumbai*

**On 6<sup>th</sup> March, 2020 (Friday, 2.30 pm – 3.30 pm)**

**CRITERIA 3.3.1**  
**PHOTO OF WORKSHOPS/SEMINARS CONDUCTED ON INTELLECTUAL PROPERTY RIGHTS (IPR) AND INDUSTRY-ACADEMIA INNOVATIVE PRACTICES DURING THE YEAR 2019-20**

**CRE ON “ADVANCED PROSTHETIC KNEE JOINTS”, DATE-13<sup>TH</sup> AUGUST 2019.**





**CRITERIA 3.3.1**  
**PHOTO OF WORKSHOPS/SEMINARS CONDUCTED ON INTELLECTUAL PROPERTY RIGHTS (IPR) AND INDUSTRY-ACADEMIA INNOVATIVE PRACTICES DURING THE YEAR 2019-20**



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**SEMINAR ON NEED BASED PRODUCT DESIGN . DATE- 6<sup>TH</sup>**  
**JANUARY-2020**



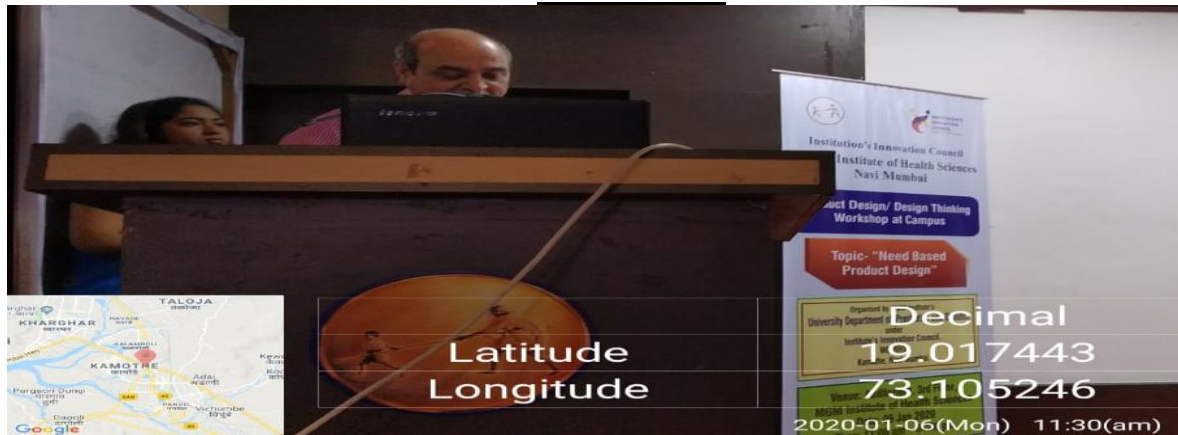
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### CRITERIA 3.3.1

## PHOTO OF WORKSHOPS/SEMINARS CONDUCTED ON INTELLECTUAL PROPERTY RIGHTS (IPR) AND INDUSTRY-ACADEMIA INNOVATIVE PRACTICES DURING THE YEAR 2019-20





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