Date: 09.08.2019 Hyderabad

To
The Dean,
Malla Reddy Medical College for Women,
Suraram
Hyderabad

From,
MEU Coordinator,
Malla Reddy Medical College for Women,
Suraram,
Hyderabad

Sub: Request to conduct add-on course on 'Good Clinical Practices'.

Respected Madam,

We are planning to conduct an add on course titled "Good Clinical Practices" for 2014 batch Interns students from August  $26^{th} - 30^{th}$  2019. The course would be conducted online using zoom platform. The details of the program are as follows:

Course coordinator: Dr Vibha Rani, Professor, Department of Pharmacology, MRMCW

#### Resource persons:

- 1. Dr Vibha Rani, Professor, Department of Pharmacology, MRMCW.
- 2. Dr N SrinivasRao, Professor, Department of General Medicine, MRMCW.
- 3. Dr B Venkatachalam, Professor & HOD, Department of Paediatrics, MRMCW.

Venue - Hospital Lecture Hall, third floor, MRNMH

Date – August 26<sup>th</sup> – 30<sup>th</sup> 2019

Time -09:00 am - 04:00 pm

We kindly request you to grant permission for the event and provide the necessary support.

Thanking you.

Malla Reddy Medical College for Wallen

Yours sincerely,

**MEU Coordinator** 



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#### MRMCW/Circulars/WADC/2019/20/Aug-02

Date: 10.08.2019

#### **CIRCULAR**

An add-on course on "Good Clinical Practices" will be conducted in Malla Reddy Medical College for Women from August  $26^{th} - 30^{th}$  2019 for 2014 batch Interns students. The course would be conducted on online platform. Students have to register with the program coordinator Dr Vibha Rani, Professor, Pharmacology.

#### Resource persons:

- 1. Dr Vibha Rani, Professor, Department of Pharmacology, MRMCW.
- 2. Dr N Srinivas Rao, Professor, Department of General Medicine, MRMCW.
- 3. Dr B Venkatachalam, Professor & HOD, Department of Paediatrics, MRMCW.

**Hyderaba** 

Venue - Hospital Lecture Hall, Third floor, MRNMH

Date -August 26th - 30th 2019

Time -09:00 am - 04:00 pm

PRINCIPAL/DEAN

Principal / Dean
Malla Reddy Medical College for Women

#### Copy to:

- 1. Circulation in student's classroom
- 2. All HoDs
- 3. Notice board
- 4. PA to Principal for filing



ADD-ON COURSE

GOOD CLINICAL PRACTICE



Course Coordinator Dr. Vibha Rani Professor - Pharmacology

For 2014 Batch interns

Organized by
Department of Pharmacology



26th - 30th August 2019

TIME: 9:00 AM TO 4:00 PM

venue: Hospital Lecture Hall, Third floor,
Malla Reddy Narayana Multispeciality Hospital

Suraram, Hyderabad.

Website: www.mrmcw.edu.in

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#### Good Clinical Practices Course objectives

COURSE	At the end of the course, the students will:		
<b>OBJECTIVES</b>	<ul> <li>Comprehending Key Concepts and Principles of Good Clinical</li> </ul>		
	Practice (GCP)		
	Developing Skills in Ethical Conduct and Regulatory Compliance		
	Enhancing Data Management and Reporting Skills		
	• Engaging in Interdisciplinary Collaboration for Clinical Research:		
	Applying Good Clinical Practice in Real-World Settings		

#### **COURSE SYLLABUS**

Module	Syllabus
MODULE 1	Overview of GCP principles and guidelines
	Importance of ethical conduct in clinical research
and the second	Regulatory framework for clinical trials
MODULE 2	Ethical Considerations in Clinical Research
	Protection of human subjects
	Ethical responsibilities of investigators, sponsors, and Institutional Review
	Boards (IRBs)
MODULE 3	Conducting Clinical Trials
1	Data collection, monitoring, and quality assurance
MODULE 4	Regulatory Compliance and Reporting
	Regulatory requirements for clinical trials (e.g., FDA, EMA)
	Adverse event reporting and safety monitoring
MODULE 5	Case studies and practical examples illustrating GCP principles
	Continuous improvement strategies for enhancing GCP adherence

#### COURSE OUTCOME

COURSE	"At the end of the course, participants will be equipped to:		
OUTCOME	<ul> <li>Understand and adhere to the principles of good clinical practice</li> <li>Implementing ethical standards in clinical research</li> <li>Demonstrating proficiency in monitoring and evaluating clinical trials</li> </ul>		
	Employ strategies for anticipating and mitigating risks in clinical settings		



Principal / Dean

Malla Reddy Medical College for Women

Coordinator

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#### **Good Clinical Practices**

#### **Programme Schedule**

Time	Program	Faculty	
Day1 (26.08.2019)		· · · · · · · · · · · · · · · · · · ·	
9am-9:30am	Registration, Pre- test	MEU Members	
9:30am to 10 am	Inauguration, Welcome Address	Dean, Vice Principal Academics, Medical Superintendent	
10am-11:00am	Introduction to Good Clinical Practice (GCP)	Dr Vibha Rani	
11:00am to 11:15am	Tea Break	•	
11:15pm to 1pm	Principles of GCP and Regulatory Framework	Dr N Srinivas Rao	
1pm-2pm	Lunch Break	43134 200 150	
2pm-4 pm	Ethics in Clinical Research Informed Consent Process and Participant Rights	Dr B Venkatachalam	
Day2 (27.08.2019)	LIGHT BOOK SAME TO SEE THE PARTY OF ASSESSMENT	None Park to the second	
9am-9:30am	Recap	MEU Members	
9:30am to 11am	Investigator Responsibilities and Site Management	Dr N Srinivas Rao	
11:00am to 11:15am	Tea Break		
11:15am to 1:00pm	Protocol Compliance and Data Integrity	Dr Vibha Rani	
1pm-2pm	Lunch Break	125/02	
2pm-3 pm	Adverse Event Reporting, Monitoring and Auditing in Clinical Trials	Dr B Venkatachalam	
3 pm - 4 pm	Interaction with students and clarifications	All resource persons	
Day 3 (28.08.2019)	*	•	
9am-9:30am	Recap	MEU Members	
9:30am to 11am	Good Documentation Practices	Dr B Venkatachalam	
11am to 11:15am	Tea Break		
11:15am to 1pm	Data Management and Quality Control	Dr N Srinivas Rao	
1pm-2pm	Lunch Break		
2pm-4pm	Statistical Considerations in Clinical Trials Investigational Product Management	Dr Vibha Rani	
	and Pharmacovigilance		
Day 4(29.08.2019)			
9am-9:30am	Recap	MEU Members	
9:30am to 11am	Regulatory Inspections and Audits	Dr B Venkatachalam	
11am to 11:15am	Tea Break		
11:15am to 1pm	Protocol Amendments and Deviations Dr Vibha Rani		

1pm-2pm	Lunch Break			
2pm-4 pm	GCP in Special Populations	Dr N Srinivas Rao		
	(Pediatrics, Geriatrics)			
	Compliance and Quality Assurance in			
	Clinical Trials			
Day 5(30.08.2019)	1			
9am-9:30am	Recap	MEU Members		
9:30am to 11am	International Standards and	Dr N Srinivas Rao		
	Harmonization in Clinical Research			
11am to 11:15am	Tea Break			
11:15am to 1pm	Ethical Considerations in Global	Dr B Venkatachalam		
	Clinical Trials			
1pm-2pm	Lunch Break			
2pm-3pm	Clinical Trial Design and	Dr Vibha Rani		
	Methodologies			
3pm-4pm	Reflections, Feedback, Post Test,	MEU Members		
	valedictory			

Coordinator

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Date: 06-09-2019

#### Report on add-on course

#### "Good Clinical Practices"

Good clinical practices (GCP) training is essential for medical graduates to uphold ethical standards and ensure the safety and well-being of patients participating in clinical trials and research studies. GCP training equips medical professionals with the knowledge and skills to conduct trials ethically, maintain data integrity, and adhere to regulatory requirements. Understanding GCP principles is crucial for ensuring the validity and reliability of research findings. Effective communication is paramount in GCP, as medical professionals must clearly convey trial protocols and risks to participants while fostering trust and transparency. GCP training cultivates resilience by preparing professionals to navigate complex ethical dilemmas and challenges inherent in clinical research. It emphasizes the importance of collaboration among multidisciplinary teams to uphold the highest standards of patient care and research integrity. Ultimately, GCP training strengthens the foundation of clinical research and enhances the credibility of medical professionals, ensuring they are well-prepared to uphold ethical standards and conduct rigorous research in their respective fields.

#### Course coordinator:

**Dr Vibha Rani**– Professor, Department of Pharmacology, Malla Reddy Medical College for Women, Suraram.

VENUE: Hospital Lecture Hall, Third floor, MRNMH

**DURATION: 35 hours** 

**TIME:**09:00 am – 04:00 pm

**DATE:**August 26<sup>th</sup> – 30<sup>th</sup> 2019

NUMBER OF PARTICIPANTS: 44 students from 2014 batch interns.

Medical,

#### Resource persons:

The key resource person for this course was Dr Vibha Rani, Professor in the Department of Pharmacology at MRMCW, who was instrumental in running the online course, with the support from Dr N Srinivas Rao (Professor in General Medicine) and Dr B Venkatachalam (Professor & HOD, Paediatrics). The course provided a comprehensive overview of good clinical values of practicing physicians.





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Good C	linical Practices	
Course Code: WADC- 19/20-05	× ·	
Date: August 26-30, 2019	Time: 9:00 am-4:00 pm	
Venue: Hospital Lecture Hall, Third floor,		
Total students registered: 44 students from		

S No	Registration number	Name of the student	Registered
1.	14804098	MittapallyLaxmiPrasanna	Yes
2.	14804099	ModalaDivya	Yes
3.	14804100	Monica Pallakonda	Yes
4.	14804102	Motukuri Suma	Yes
5.	14804103	MunnangiLikhitha	Yes
6.	14804104	N Shreya	Yes
7.	14804106	Nalla Šai Lakshmi Pravallika	Yes
8.	14804108	Neha	Yes
9.	14804109	Neha Samreen	Yes
10.	14804110	Nikita Singh	Yes
11.	14804111	NouleGouthami	Yes
12.	14804112	P Pavani	Yes
13.	14804114	Panchumarthy Pragna	Yes
14.	14804117	PonduruKavya	Yes
15.	14804118	PoreddyMounica Reddy	Yes
16.	14804119	Pratima Dhurka	Yes
17.	14804120	Prerna	Yes
18.	14804121	PunnatiChaitanya	Yes
19.	14804122	PurraNishaYadav	Yes
20.	(4804123 (2) (1) (1) (1) (2) (2)	W   R Ihansi Amriitha	Yes

21.	14804124	RajapudiMounika	Yes
22.	14804125	ReddiRinita	Yes
23.	14804127	Sai Manojna TLBNM	Yes
24.	14804128	Samreen Fatima	Yes
25.	14804129	SanjanaMareddy	Yes
26.	14804131	Seelam Pratyusha	Yes
27.	14804132	Shastri Lakshmi Sindhuri	Yes
28.	14804133	SingamneniHarsha	Yes
29.	14804134	Sri Lekha Yarlagadda	Yes
30.	14804135	SrivaniSherikari	Yes
31.	14804136	Swathi K	Yes
32.	14804137	T Anna Rachel Supriya	Yes
33.	14804138	Thakur Siri Singh	Yes
34.	14804139	ThoudojuNavya	Yes
35.	14804140	ToletyMounica	Yes
36.	14804141	UbbuKavery	Yes
37.	14804142	UdataPranavi	Yes
38.	14804143	Vadde Sumitha	Yes
39.	14804144	Vaishnavi Nama	Yes
40.	14804145	VarthiyaAishwarya	Yes
41.	14804146	VeerlapatiPriyanka	Yes
42.	14804147	VelganiShivangi	Yes
43.	14804148	VinukondaAnusha	Yes
44.	14804150	YerukalaNavaneetha	Yes
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Good Clinical Practices			
Course Code: WADC- 19/20-05			
Date: 26 -30 August 2019	Time: 9:00 am-4:00 pm		
Venue: Hospital Lecture Hall, Third floor, MR	NMH		
Total students completed: 43 students from 20			

S No	HTNO	Name	Successfully completed
1.	14804098	MittapallyLaxmiPrasanna	Yes
2.	14804099	ModalaDivya	Yes
3.	14804100	Monica Pallakonda	Yes
4.	14804102	Motukuri Suma	Yes
5.	14804103	MunnangiLikhitha	Yes
6.	14804104	N Shreya	Yes
7.	14804106	Nalla Sai Lakshmi Pravallika	Yes
8.	14804108	Neha	Yes
9.	14804109	Neha Samreen	Yes
10.	14804110	Nikita Singh	Yes
11.	14804111	NouleGouthami	Yes
12.	14804112	P Pavani	Yes
13.	14804114	Panchumarthy Pragna	Yes
14.	14804117	PonduruKavya	Yes
15.	14804118	PoreddyMounica Reddy	Yes
16.	14804119	Pratima Dhurka	Yes
17.	14804120	Prerna	Yes
18.	14804121	PunnatiChaitanya	Yes
19.	14804122	PurraNishaYadav	Yes

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Principal / Dean

Suraram 'x' Road, Quthbullapur Municipality, Jeedimetla, Hyderabad - 500 055. Tel: 040-64583333, Website: www.mrmcw.org

20.	14804123	R Jhansi Amrutha	Yes
21.	14804124	RajapudiMounika	Yes
22.	14804125	ReddiRinita	Yes
23.	14804127	Sai Manojna TLBNM	Yes
24.	14804128	Samreen Fatima	Yes
25.	14804129	SanjanaMareddy	Yes
26.	14804131	Seelam Pratyusha	Yes
27.	14804132	Shastri Lakshmi Sindhuri	Yes
28.	14804133	SingamneniHarsha	Yes
29.	14804134	Sri Lekha Yarlagadda	Yes
30.	14804135	SrivaniSherikari	Yes
31.	14804136	Swathi K	Yes
32.	14804137	T Anna Rachel Supriya	Yes
33.	14804138	Thakur Siri Singh	Yes
34.	14804139	ThoudojuNavya	Yes
35.	14804140	ToletyMounica	Yes
36.	14804141	UbbuKavery	No
37.	14804142	UdataPranavi	Yes
38.	14804143	Vadde Sumitha	Yes
39.	14804144	Vaishnavi Nama	Yes
40.	14804145	VarthiyaAishwarya	Yes
41.	14804146	VeerlapatiPriyanka	Yes
42.	14804147	VelganiShivangi	Yes
43.	14804148	VinukondaAnusha	Yes
44.	14804150	YerukalaNavaneetha	Yes
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### CERTIFICATE

Mr./Ms. MITTAPALLY LAXMI PRASANNA ,
Intern of MBBS, bearing roll no: 14804098
has successfully completed the Add on Course
- "Good Clinical Practices", conducted in the
institute from 26<sup>th</sup> Aug to 30<sup>th</sup> Aug 2019.

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### CERTIFICATE

Mr./Ms. MODALA DIVYA

Intern of MBBS, bearing roll no: <u>14804099</u> has successfully completed the Add on Course – "Good Clinical Practices", conducted in the institute from 26<sup>th</sup> Aug to 30<sup>th</sup> Aug 2019.

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O. Wellerha Principal / Dean

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### CERTIFICATE

Mr./Ms. MONICA PALLAKONDA

Intern of MBBS, bearing roll no: 14804100

has successfully completed the Add on Course

- "Good Clinical Practices", conducted in the institute from 26<sup>th</sup> Aug to 30<sup>th</sup> Aug 2019.

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### CERTIFICATE

Mr./Ms. MOTUKURI SUMA

Intern of MBBS, bearing roll no: 14804102 has successfully completed the Add on Course – "Good Clinical Practices", conducted in the institute from 26<sup>th</sup> Aug to 30<sup>th</sup> Aug 2019.

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### CERTIFICATE

Mr./Ms. MUNNANGI LIKHITHA

Intern of MBBS, bearing roll no: <u>14804103</u>
has successfully completed the Add on Course
- "Good Clinical Practices", conducted in the

institute from 26th Aug to 30th Aug 2019.

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### CERTIFICATE

Mr./Ms. N SHREYA

Intern of MBBS, bearing roll no: 14804104 has successfully completed the Add on Course – "Good Clinical Practices", conducted in the institute from 26<sup>th</sup> Aug to 30<sup>th</sup> Aug 2019.

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### CERTIFICATE

Mr./Ms. NALLA SAI LAKSHMI PRAVALLIKA, Intern of MBBS, bearing roll no: 14804106 has successfully completed the Add on Course – "Good Clinical Practices", conducted in the institute from 26<sup>th</sup> Aug to 30<sup>th</sup> Aug 2019.

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#### CERTIFICATE

Mr./Ms.NEHA

Hyderabad)

Intern of MBBS, bearing roll no: 14804108 has successfully completed the Add on Course – "Good Clinical Practices", conducted in the institute from 26<sup>th</sup> Aug to 30<sup>th</sup> Aug 2019.

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### CERTIFICATE

Mr./Ms. NEHA SAMREEN

Intern of MBBS, bearing roll no: 14804109 has successfully completed the Add on Course – "Good Clinical Practices", conducted in the institute from 26<sup>th</sup> Aug to 30<sup>th</sup> Aug 2019.

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### CERTIFICATE

Mr./Ms. NIKITA SINGH

Intern of MBBS, bearing roll no: 14804110 has successfully completed the Add on Course – "Good Clinical Practices", conducted in the institute from 26<sup>th</sup> Aug to 30<sup>th</sup> Aug 2019.

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### CERTIFICATE

Mr./Ms. NOULE GOUTHAMI

Intern of MBBS, bearing roll no: 14804111 has successfully completed the Add on Course

- "Good Clinical Practices", conducted in the institute from 26th Aug to 30th Aug 2019.

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#### CERTIFICATE

Mr./Ms. P PAVANI

Intern of MBBS, bearing roll no: 14804112 has successfully completed the Add on Course – "Good Clinical Practices", conducted in the institute from 26<sup>th</sup> Aug to 30<sup>th</sup> Aug 2019.

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### CERTIFICATE

Mr./Ms. PANCHUMARTHY PRAGNA

Intern of MBBS, bearing roll no: 14804114

has successfully completed the Add on Course

- "Good Clinical Practices", conducted in the institute from 26<sup>th</sup> Aug to 30<sup>th</sup> Aug 2019.

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### CERTIFICATE

Mr./Ms. PONDURU KAVYA

Intern of MBBS, bearing roll no: 14804117 has successfully completed the Add on Course – "Good Clinical Practices", conducted in the institute from 26<sup>th</sup> Aug to 30<sup>th</sup> Aug 2019.

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### CERTIFICATE

Mr./Ms. POREDDY MOUNICA REDDY
,
Intern of MBBS, bearing roll no: 14804118
has successfully completed the Add on Course
- "Good Clinical Practices", conducted in the institute from 26<sup>th</sup> Aug to 30<sup>th</sup> Aug 2019.

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### CERTIFICATE

Mr./Ms. PRATIMA DHURKA

Intern of MBBS, bearing roll no: 14804119 has successfully completed the Add on Course – "Good Clinical Practices", conducted in the institute from 26<sup>th</sup> Aug to 30<sup>th</sup> Aug 2019.

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### CERTIFICATE

Mr./Ms. PRERNA

Intern of MBBS, bearing roll no: 14804120 has successfully completed the Add on Course - "Good Clinical Practices", conducted in the institute from 26th Aug to 30th Aug 2019.

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### CERTIFICATE

Mr./Ms. PUNNATI CHAITANYA

Intern of MBBS, bearing roll no: 14804121 has successfully completed the Add on Course – "Good Clinical Practices", conducted in the institute from 26<sup>th</sup> Aug to 30<sup>th</sup> Aug 2019.

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Mr./Ms. PURRA NISHA YADAV

Intern of MBBS, bearing roll no: 14804122 has successfully completed the Add on Course – "Good Clinical Practices", conducted in the institute from 26<sup>th</sup> Aug to 30<sup>th</sup> Aug 2019.

Sical Co Coordinator

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Principal/Dean

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### CERTIFICATE

Mr./Ms. R JHANSI AMRUTHA

Intern of MBBS, bearing roll no: 14804123 has successfully completed the Add on Course – "Good Clinical Practices", conducted in the institute from 26<sup>th</sup> Aug to 30<sup>th</sup> Aug 2019.

Coordinator

Principal/Dean

Sherlaha

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### CERTIFICATE

Mr./Ms. RAJAPUD IMOUNIKA

Intern of MBBS, bearing roll no: 14804124 has successfully completed the Add on Course – "Good Clinical Practices", conducted in the institute from 26<sup>th</sup> Aug to 30<sup>th</sup> Aug 2019.

Coordinator

Principal/Dean

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#### CERTIFICATE

Mr./Ms. REDDI RINITA

Intern of MBBS, bearing roll no: 14804125 has successfully completed the Add on Course - "Good Clinical Practices", conducted in the institute from 26th Aug to 30th Aug 2019.

Coordinator

Principal/Dean

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### CERTIFICATE

Mr./Ms. SAI MANOJNA TLBNM

Intern of MBBS, bearing roll no: 14804127

has successfully completed the Add on Course

- "Good Clinical Practices", conducted in the institute from 26th Aug to 30th Aug 2019.

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Principal/Dean

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### CERTIFICATE

Mr./Ms. SAMREEN FATIMA

Intern of MBBS, bearing roll no: <u>14804128</u> has successfully completed the Add on Course – "Good Clinical Practices", conducted in the institute from 26<sup>th</sup> Aug to 30<sup>th</sup> Aug 2019.

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### CERTIFICATE

Mr./Ms. SANJANA MAREDDY

Intern of MBBS, bearing roll no: 14804129 has successfully completed the Add on Course – "Good Clinical Practices", conducted in the institute from 26<sup>th</sup> Aug to 30<sup>th</sup> Aug 2019.

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#### CERTIFICATE

Mr./Ms. SEELAM PRATYUSHA

Intern of MBBS, bearing roll no: 14804131

has successfully completed the Add on Course

- "Good Clinical Practices", conducted in the institute from 26<sup>th</sup> Aug to 30<sup>th</sup> Aug 2019.

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### CERTIFICATE

Mr./Ms. SHASTRI LAKSHMI SINDHURI, Intern of MBBS, bearing roll no: 14804132 has successfully completed the Add on Course – "Good Clinical Practices", conducted in the institute from 26th Aug to 30th Aug 2019.

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### CERTIFICATE

Mr./Ms. SINGAMNENI HARSHA

Intern of MBBS, bearing roll no: 14804133 has successfully completed the Add on Course – "Good Clinical Practices", conducted in the institute from 26<sup>th</sup> Aug to 30<sup>th</sup> Aug 2019.

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### CERTIFICATE

Mr./Ms. SRI LEKHA YARLAGADDA

Intern of MBBS, bearing roll no: 14804134

has successfully completed the Add on Course

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### CERTIFICATE

Mr./Ms. SRIVANI SHERIKARI

Intern of MBBS, bearing roll no: 14804135 has successfully completed the Add on Course

- "Good Clinical Practices", conducted in the institute from 26th Aug to 30th Aug 2019.

Coordinator

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