

10/16/2017

Chennai

From

Mrs. D. Bindu, Assistant Professor  
Bharath Institute of Higher Education and Research,  
Chennai

To

The Dean  
Sree Balaji Medical College  
Bharath Institute of Higher Education Research,  
Chennai

**Sub: -Permission to conduct value-added course: The Design and Interpretation of Clinical Trials on, 10/26/2017**

Respected sir,

With reference to subject mentioned above, the department proposes to conduct a value-added course titled: The Design and Interpretation of Clinical Trials

We kindly solicit your kind permission to commence the program.

Warm Regards,

Course Coordinator



Mrs. D. Bindu, Assistant Professor

**Sree Balaji Medical College & Hospital,  
SCHOOL OF ALLIED HEALTH SCIENCES  
Chennai - 600 044**

Date: 10/19/2017

**CIRCULAR**

**Notification for Value added courses offered by the School of Allied Health  
Sciences**

The School of Allied Health Sciences is scheduled to offer a Value added Certificate Course on The Design and Interpretation of Clinical Trials from 10/26/2017 for a period of 2 weeks. Interested students can approach Mrs. D. Bindu, Assistant Professor and Course Coordinator, School of Allied Health Sciences for registration and for further details on or before 10/20/2017

**Eligibility-II, III and IV B Sc AHS students**



DEAN

Copy to:

Vice Chancellor

Pro Vice Chancellor

Additional Registrar

Deans

CoE

Heads of Departments

**Sree Balaji Medical College & Hospital,  
SCHOOL OF ALLIED HEALTH SCIENCES  
Chennai - 600 044**

**VALUE ADDED COURSE -The Design and Interpretation of Clinical Trials**

**COURSE CO-ORDINATOR DETAILS**

**Faculty Name :** Mrs. D. Bindu, Assistant Professor

**Email ID:** [bindu.d@bharathuniv.ac.in](mailto:bindu.d@bharathuniv.ac.in)

**Mobile number:** 9841255807

<b>SCHOOL OF ALLIED HEALTH SCIENCES</b>				
<b>VALUE ADDED COURSE ON THE DESIGN AND INTERPRETATION OF CLINICAL TRIALS</b>				
<b>40 HOURS - ONLINE CLASS</b>				
<b>UNIT -1 – INTRODUCTION TO CLINICAL TRIALS</b>				
<b>MODULE</b>	<b>TOPIC</b>	<b>HOURS</b>	<b>TEACHING METHODOLOGY</b>	<b>FACULTY</b>
1	Introduction to clinical trials and study protocols	1	Lecture	AHS asst Professor
2	Brief overview study protocol features	2	Lecture	
3	Intervention, study population and study endpoints	1	Lecture	
4	Research questions/hypotheses (FINER criteria)	1	Lecture	
5	Assessment	1	MCQs	Tutor
<b>UNIT -2 – INTRODUCTION TO PHASE I &amp; II TRIALS &amp; INTRODUCTION TO PHASE III TRIALS</b>				
<b>MODULE</b>	<b>TOPIC</b>	<b>HOURS</b>	<b>TEACHING METHODOLOGY</b>	<b>FACULTY</b>
1	Overview of Phase I studies	1	Lecture	AHS Tutor
2	Overview of Phase II studies	1	Lecture	
3	Introduction to Phase III trials	2	Lecture	
4	Protocol development guidelines	2	Lecture	
5	Assessment	1	MCQs	AHS Tutor
<b>UNIT -3 – IMPORTANT PROCEDURES IN CLINICAL TRIALS ETHICS IN CLINICAL TRIALS</b>				

MODULE	TOPIC	HOURS	TEACHING METHODOLOGY	FACULTY
1	Randomization	2	Lecture	AHS Assistant Professor
2	Intent-to-treat concept, Blinding/Masking, Placebo controls	2	Lecture	
3	Ethical issues in clinical trials	2		Community medicine tutor
4	Assessment	1	MCQs	Tutor
<b>UNIT -4 – STUDY COORDINATION &amp; RECRUITMENT, ADVERSE EVENTS AND ADHERENCE</b>				
MODULE	TOPIC	HOURS	TEACHING METHODOLOGY	FACULTY
1	Recruitment and retention	2	Lecture	CRO manager
	Barriers to participation in research	2		
2	Adverse event reporting	2	Lecture	
	Adherence	2		
3	Assessment	1	MCQs	Tutor
<b>UNIT -5 – DATA AND SAFETY MONITORING, INTRODUCTION TO INTERIM ANALYSES</b>				
MODULE	TOPIC	HOURS	TEACHING METHODOLOGY	FACULTY
1	Study monitoring	2	Lecture	CRO
2	Understand the role of a data and safety monitoring board (DSMB)	2	Lecture	
3	Introduction to interim analysis	2	Lecture	
4	Early termination	1	Lecture	
5	Protocol deviations	1	Lecture	
	Study closeout			

6		1		
7	Reporting study results & Authorship guidelines in protocols	1		
8	Assessment	1	MCQs	Tutor

BHARATH INSTITUTE OF HIGHER EDUCATION AND RESEARCH

SCHOOL OF ALLIED HEALTH SCIENCES

VALUE ADDED COURSE

THE DESIGN AND INTERPRETATION OF CLINICAL TRIALS [2017- 2018]

Students Name List

S.No	Reg No	Name
1	PM17 CVT 035	Sneha Rose Mathew
2	PM 17 RDT 137	Pooja Prakash
3	PM17 CVT 035	Sneha Rose Mathew
4	PM17 CVT 036	Sowmiya M
5	PM17 CVT 037	Subina Sen S
6	PM17 CVT 038	Suhail.P.P
7	PM17 CVT 039	Sushena Jain M
8	PM 17 RDT 133	Hari Priya M
9	PM 17 RDT 134	Irshad K P
10	PM 17 RDT 135	Mohammed Arshad A C
11	PM 17 RDT 136	Pandiyan M
12	PM 17 RDT 138	Pooja Prashanth
13	PM 17 RDT 140	Safna Fathima A
14	PM 17 RDT 143	Surya B
15	PM 17 RDT 144	Sushmitha V
16	PM 17 RDT 145	Yogeshwari S
17	PM 17 RDT 146	Yokesh Kumar B
18	PM17 RCT 150	Praveena S
19	PM17 RCT 152	Solomon S Melit
20	PM17 CPT 061	Lavanya Venu C
21	PM17 CPT 063	Mariya Riya
22	PM17 CPT 067	Sairam V
23	PM17 CPT 072	Vikram R
24	PM17 MLT 079	Swathi S

25	PM17 MLT 081	Trinita G
26	PM17 RIST 117	Alphin K Sunny
27	PM17 RIST 119	Bharathi S
28	PM17 RIST 122	Mohamed Asif S
29	PM17 RIST 126	Prabhakaran S
30	PM17 OTAT 112	Vijaya Preetha S
31	PM17 OTAT 114	Vinitha Sakthi P
32	PM17 CVT 001	AL Junaid S S
33	PM17 CVT 003	Aishwariya M
34	PM17 CVT 006	Anshad. S
35	PM17 CVT 010	Baby Lakshmi R
36	PM17 OTAT 092	Harisa S
37	PM17 CPT 049	Deepika R
38	PM17 CPT 050	Divya K
39	PM17 CPT 051	Gayathri K
40	PM17 CPT 054	Iswarya D
41	PM17 CPT 065	Muhammed Nidal
42	PM17 CPT 066	Punithavathy L
43	PM 17 RDT 142	Shruthi
44	PM17 OTAT 110	ELDHOSE SHIBU
45	PM17 CVT 029	Roshan Fathima S



CORSE FEEDBACK FORM

Date:

Course Title: *Design & Interpretation of clinical Trials*

Name: *Subina Sen S*

RegNo: *PMHCVT037*

Department: *CVT*

S.NO	Particulars	1	2	3	4	5
(1. Very Unsatisfied 2. Unsatisfied 3. Neutral 4. Satisfied 5. Very satisfied)						
1.	Objectives of the course clear to you			✓		
2.	The course contents met with your expectations				✓	
3.	The lecture sequence was well planned				✓	
4.	The lecturers were clear and easy to understand			✓		
5.	The teaching aids were effective				✓	
6.	The instructors encourage interaction and were helpful				✓	
7.	The level of the course					
(1. Very poor 2. Poor 3. Average 4. Good 5. Excellent )						
8.	Overall rating of the course:				✓	

Please give suggestion for the improvement of the course:

Weakness of the course:

Strength of the course:

*Subina*  
Signature

\*\*\*Thank you\*\*\*

CORSE FEEDBACK FORM

Course Title: *Design & Interpretation of clinical*  
Name: *Sohail P. P* *Trials*  
RegNo: *PMCT CVT 039*  
Department: *CVT*

Date:

S.NO	Particulars	1	2	3	4	5
(1. Very Unsatisfied 2. Unsatisfied 3. Neutral 4. Satisfied 5. Very satisfied)						
1.	Objectives of the course clear to you		✓			
2.	The course contents met with your expectations		✓			
3.	The lecture sequence was well planned			✓		
4.	The lecturers were clear and easy to understand				✓	
5.	The teaching aids were effective					
6.	The instructors encourage interaction and were helpful		✓	✓		
7.	The level of the course					✓
(1. Very poor 2. Poor 3. Average 4. Good 5. Excellent )						
8.	Overall rating of the course:	1	2	3	✓ 4	5

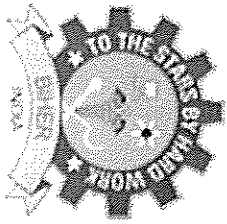
Please give suggestion for the improvement of the course:

Weakness of the course:

Strength of the course:

*Sohail P. P*  
Signature

\*\*\*Thank you\*\*\*




**Bharath Institute of Higher Education and Research  
Sree Balaji Medical College & Hospital**



**SCHOOL OF ALLIED HEALTH SCIENCES**  
***Certificate of Participation***

This is to certify that Mr /Ms. Sneha Rose Mathew(PM17 CVT 035)  
has attended two weeks Value added Course on The Design & Interpretation of Clinical Trials conducted by,  
School of Allied Health Sciences

  
**Dr WMS Johnson**  
Vice Principal

  
**Dr P Saikumar**  
Dean



**Conducted value added course in The Design and Interpretation of Clinical Trials on 10/26/2017**