

Faculty of Pharmacy, SBMCH campus, Chromepet, BIHER

Name of the Value added course

**CERTIFICATE COURSE IN CLINICAL TRIALS IN INDIA FOR
INVESTIGATION OF NEW DRUGS – VAC20/BP/2023-09/05**

Course Code	Course Outcomes
CO 1	Providing the knowledge about the overview of new drugs and clinical trial rules.
CO 2	Learning about good clinical trial practice
CO 3	Detailing about NDCT rules.
CO4	Learning about the abbreviations

Module I: Course overview of New drugs and clinical trial rules

- Course overview, overview of Indian drug regulatory system. Overview of drugs & cosmetics Act and rules there under, overview of new drug and clinical trial rules, 2019, pre-clinical data requirements, rules governing clinical trial, phases of clinical trial, forms, and fees, regulatory pathway and data requirements for NDCT-2019.

Module II: Import/manufacture of new drugs for conducting CT

- BA/BE study and study centres: Legal provisions. Guidelines to conduct BA/BE studies, Ethics Committee registration and re-registration. Ethical considerations, Good clinical practice, Requirements for import /manufacture of new drug/IND for conducting clinical trials in india , requirements for import /manufacture of new drug/IND for sale/distribution and unapproved new drug for patients

Module III: Clinical trial related guidelines(NDCT Rules)

- Important issues, special concerns. Clinical trial related guidelines (NDCT Rules), content of proposed clinical trial protocol. Content of a clinical trial protocol. Content of a clinical report. Post marketing assessment and clinical trial compensation.

Module IV:

- Common observations during submission of CT/BA/BE protocol. Common Observations during CT/BA/BE centre inspections. Drugs development process: overview. salient feature of NDCT 2019(What 's new in NDCT?). Online submission (CTRI). Tables given in NDCT N2019 and its content.

Total contact hours: 32

Reference Books

- [https://edsco.gov.in/openems/export/sites/CDSCO/WEB/pdf-documents/NewDrugsCI Rules 2019.pdf](https://edsco.gov.in/openems/export/sites/CDSCO/WEB/pdf-documents/NewDrugsCI%20Rules%202019.pdf)
- <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7034142/>

Course outcome evaluation

Course code	Course outcomes	Evaluation
CO 1	Providing the knowledge about the overview of new drugs and clinical trial rules.	Formative Assignments and communication skills
CO 2	Learning about good clinical trial practice	Formative Assignments and critical thinking
CO 3	Detailing about NDCT rules.	Formative Assignments and understanding , thinking skills
CO4	Learning about the abbreviations	Formative Assignments and critical thinking



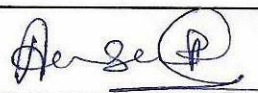
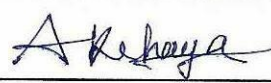

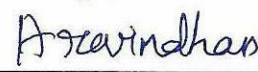
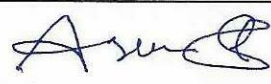
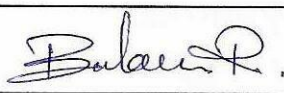
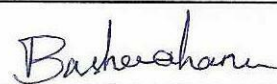
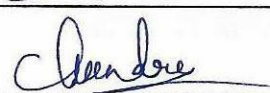
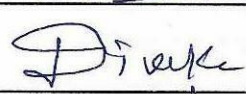
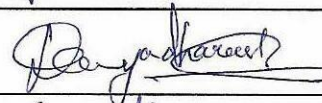
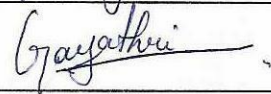
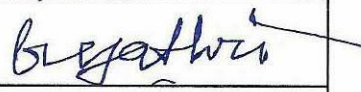

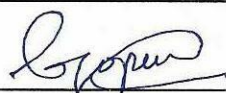
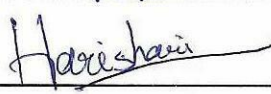
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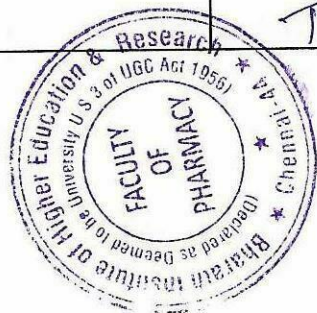
VALUE ADDED COURSE 2023 - 2024

FACULTY OF PHARMACY , BIHER,SBMCH Campus, CHENNAI -44
 CERTIFICATE COURSE IN CLINICAL TRIALS IN INDIA FOR
 INVESTIGATION OF NEW DRUGS

STUDENTS LIST

1	AGLIN SUBI RAJ P.S.	
2	AKSHAYA MU.	
3	ANTONY ARUN JOSEPH U	
4	ARAVINDHAN K.	
5	ASWINI S.	
6	BALAMBIGAI R	
7	BASHEER AHAMED H	
8	CHANDRAN V.	
9	DIVAKAR .V	
10	DIVYADHAARSHINI R.	
11	GAYATHRI M	
12	GAYATHRI R	
13	GEETHANJALI C.	
14	GOPINATH T.	
15	HARI SHANKAR R A	

16	HARISHREE R.	Harishree R.
17	HEMA ROHINI K.M	Hema Rohini K.M
18	HOSANNA JACOB EZEKIEL B.	Hosanna Jacob Ezekiel B.
19	KARTHIKRAJA S.	Karthik Raja S.
20	KISHORE KUMAR P	Kishore Kumar P.
21	KISHORE R.	Kishore R.
22	MUTHULAKSHMI V.M.	Muthulakshmi V.M.
23	NANCY LIVIEN SWETHA	Nancy Livien Swetha
24	PAVITHRA T	Pavithra T.
25	PONNIYAMMAL M.	Ponniyammal M.
26	PREDHISHA S.	Predhisha S.
27	PRIYANKAA V	Priyanka V.
28	RAJA GANESAN R.	Raja Ganesan R.
29	RAJALAKSHMI S	Rajalakshmi S.
30	RISHIKA A.	Rishika A.
31	SANGEETHA M	Sangeetha M.
32	SATHISH K	Sathish K.
33	SELVA S.	Selva S.
34	SHEETHAL P.	Sheethal P.
35	TAMILAN S.	Tamilan S.



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36	TAMILVANI R.	Tamilvani R.
37	UZAIR AHMAD DAR	Uzair Ahmad
38	VARSHINI S.	Varshini S.
39	VASANTH GANESH	Vasanth Ganesh
40	VIKAS S.	Vikas S.
41	MADHUMITHA S	Madhumitha S.
42	ATCHAYA R.	Atchaya R.
43	BALASUBRAMANIYAN P.	Balasubramanian P.
44	DHATCHAINI S.	Dhatchaini S.
45	DHIVYADHARSINI Y.	Dhivyadharsini Y.
46	GOKULAKRISHNAN H.	Gokulakrishnan H.
47	GOMATHI S.	Gomathi S.
48	HARI PRASAD S.	Hari Prasad S.
49	KAVIYA R	Kaviya R.
50	KEERTHANA M	Keerthana M.
51	LAKSHMI PRIYA S.	Lakshmi Priya S.
52	MONISH M.	Monish M.
53	PARVEEN KUMAR B.	Parveen Kumar B.
54	PRAMOTH KUMAR V.	Pramoth Kumar V.
55	RAJKUMAR E.	Rajkumar E.

56	RAMYA B.	<i>Ramya</i>
57	SANJAI S.	<i>Sanjai</i>
58	SRI JAYAKRIPA SAGARI P.	<i>Sri Jayakripa</i>
59	SETHUPATHY S.	<i>Sethupathy</i>
60	SYED ABDULLAH FAHATH T.	<i>Abdul Fahath</i>
61	VETRI SELVAN V.	<i>Vetri Selvan</i>

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FACULTY OF PHARMACY
SREE BALAJI MEDICAL COLLEGE & HOSPITAL CAMPUS
BHARATH INSTITUTE OF HIGHER EDUCATION & RESEARCH
CHROMEPET CHENNAI – 600044

VALUE ADDED COURSE

2022-2023

**CERTIFICATE COURSE IN CLINICAL TRIALS IN INDIA FOR INVESTIGATION OF NEW
DRUGS
RESOURCE PERSON DETAILS**

Faculty Name: Dr.P.K.Anamika, Associate Professor, Department of Pharmacology

Mail ID: anamika.pharm@bharathuniv.ac.in

Mobile: 9500873303



Date: 06/02/2023

From

Dr.P.K.Anamika
Course Coordinator
Department of Pharmacology
Faculty of Pharmacy, SBMCH,
Bharath Institute of Higher Education & Research,
Chromepet, Chennai – 600044

To

The Dean
Faculty of Pharmacy, SBMCH,
Bharath Institute of Higher Education & Research,
Chromepet Chennai – 600044

Subject: Grand Permission for Value Added Course –CERTIFICATE COURSE IN CLINICAL TRIALS IN INDIA FOR INVESTIGATION OF NEW DRUGS– Request Reg.

Respected Sir

On behalf of the Department of Pharmacology, we wish to conduct Value added COURSES ON CERTIFICATE COURSE IN CLINICAL TRIALS IN INDIA FOR INVESTIGATION OF NEW DRUGS for Pharmacy students on 06/03/2023. So kindly permit me to conduct the same.

P.K. Anamika
COURSE COORDINATOR

Approved
J. Anand



FACULTY OF PHARMACY
SREE BALAJI MEDICAL COLLEGE & HOSPITAL CAMPUS
BHARATH INSTITUTE OF HIGHER EDUCATION & RESEARCH
CHROMEPET, CHENNAI – 600044

Date: 15/02/2023

Ref.No: 071/FCP-VAC/2023

CIRCULAR

Notification for Value Added Courses

Faculty of Pharmacy, Sree Balaji Medical College & Hospital Campus is scheduled to offer a Value added Course –CERTIFICATE COURSE IN CLINICAL TRIALS IN INDIA FOR INVESTIGATION OF NEW DRUGS 06/03/2023 for a period of 12 weeks. Interested students can approach the Department of Pharmacology and course coordinator for registration and for further details on or before 03/03/2023

Eligibility – Pharmacy Students


Course Coordinator



HOD

Copy to:

Dean / Principal Office

Registrar

AO College



COURSE FEEDBACK FORM

Course Title: Certificate Course in clinical trials in India for Investigation of New Drugs Date: 11.05.2023

Name: Divakar V

Reg No:

Department: pharmacology

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. Neutral 4. Satisfied 5. Very Satisfied)						
8.	Overall rating of the course					✓

Please give suggestion for the improvement of the course:

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Weakness of the Course:

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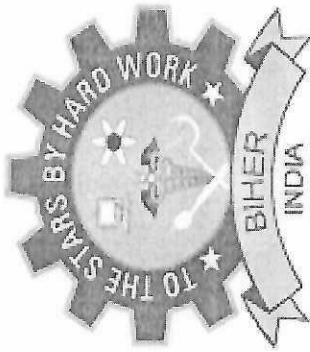
Strength of the course:

—

Divakar V
Signature

Janak





Sri Balaji

INSTITUTE OF HIGHER EDUCATION AND RESEARCH

(Declared as Deemed - to - be - University under section 3 of UGC Act 1956)

FACULTY OF PHARMACY

SREE BALAJI MEDICAL COLLEGE & HOSPITAL CAMPUS

CHROMEPET, CHENNAI - 600044

This is to certify that Mr./Ms. Nerti Selvan. V. has completed the value added
Certificate Course in clinical
course on trials in India for Investigative conducted by Dr. P.K. Anantika. at Faculty of
of New Drugs

Pharmacy, Sree Balaji Medical College & Hospital campus, Chromepet, Chennai held during 2022 - 2023.

P.K. Anantika
COURSE COORDINATOR



P. Anantika

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