



(An Autonomous Institution - AFFILIATED TO ANNA UNIVERSITY, CHENNAI)

S.P.G.Chidambara Nadar - C.Nagammal Campus

S P G C. Nagar, K Vellakulam - 625 701 (Near VIRUDHUNAGAR)

DEPARTMENT OF BIOTECHNOLOGY

Industry Certified Value-Added Course

On

CLINICAL RESEARCH AND PHARMACOVIGILANCE

In Association with Deepam Hospitals, Urapakkam, Chennai.

06 – 09 February 2023

1. Academic Year : 2022-23
2. Regulation : R2020
3. Department Name : Biotechnology
4. Name of the Value-added Course : Industry Certified Value-Added Course on “**Clinical Research and Pharmacovigilance**”
5. Number of Credits : 02
6. Theory / Lab / Hands-on / Skill based : Hands-on & Skill Based
7. Joint Organization : Deepam Hospitals, Urapakkam, Chennai.
8. Resource Person Details :
 1. Mr. Rajavelu, Deepam Academy of Medical Sciences, Chennai
 2. Mr. Dhayalan, Deepam Academy of Medical Sciences, Chennai
9. Three Member Committee :
 1. Dr. R. Shyam Kumar, HOD/BT
 2. Dr. A. Ronaldo Anuf, AP/BT
 3. Er. Karl Joseph Samuel, AP/BT
10. Program Coordinators :
 1. Dr. R. Baskaran, ASP/BT
 2. Dr. A. Ronaldo Anuf, AP/BT
 3. Er. Karl Joseph Samuel, AP/BT
11. Duration (30h Mandatory) : 32 Hours
12. Period : 06-02-2023 to 09-02-2023 (4 Days)
13. Venue : Department of Biotechnology,
Kamaraj College of Engineering and Technology,
S.P.G.C. Nagar,
K. Vellakulam (Near Virudhunagar) - 625701


Coordinators


Dean (Academic Courses)


HOD / BT



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DEPARTMENT OF BIOTECHNOLOGY

Industry Certified Value-Added Course

On

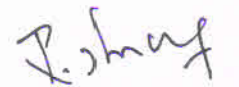
CLINICAL RESEARCH AND PHARMACOVIGILANCE

In Association with Deepam Hospitals, Urapakkam, Chennai.

Enclosures:

S. No	Particulars	Availability
1.	Institution Approval Copy	Yes
2.	Circular	Yes
3.	Syllabus Copy with Course Outcomes	Yes
4.	BoS Approval	Yes
5.	Three Member Committee MoM	Yes
6.	Geo-Tagged Photos	Yes
7.	Certificates of All Participants	Yes
8.	Examination Schedule	Yes
9.	Question & Answer Keys	Yes
10.	Attendance Sheet	Yes
11.	Evaluated Answer Scripts	Yes
12.	Test Report	Yes
13.	Mark Statement	Yes
14.	Grade Sheet	
15.	Feedback Form	Yes
16.	Feedback Analysis & Report	Yes
17.	Program Summary Report	Yes
18.	Students Oral Feedback (Video)	
19.	VAC - Short Video	


Coordinators


HOD / BT

KAMARAJ

COLLEGE OF ENGINEERING & TECHNOLOGY

S.P.G.Chidambara Nadar - C. Nagammal Campus,
S.P.G.C. Nagar, K. Vellakulam - 625 701, Near VIRUDHUNAGAR, Madurai District.

Accredited by NAAC with 'A' Grade



Submitted to the SECRETARY for approval through the PRINCIPAL

Book No.

BIOTECH

SL No. 65

Date 21/02/2023.....

Approval for Value Added Program for III BT
(2022-2023)

Approval may please be granted to conduct Value added program on "Clinical Research and Pharmacovigilance" from 6th to 9th February 2023 (4 days) for III B.Tech Biotech students as a Industry Certified Program. The proposal and budget is attached for Verification. The budget is Rs. 49,800/- . We request you to provide food, refreshment and accommodations for 2 resource persons from 06.02.2023 to 09.02.2023.

Kindly give us permissions to conduct the same.

1. do nothing

2. do nothing

3. do nothing
Signature of Faculty

HOD

Principal
2/2/23
PRINCIPAL

OFFICE USE

1) Budget allotted

: Value Added Course

2) Amount committed / Spent so far

:

3) Balance available

:

OM

Treasurer

Secretary



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DEPARTMENT OF BIOTECHNOLOGY
Industry Certified Value-Added Course
On
CLINICAL RESEARCH AND PHARMACOVIGILANCE

In association with

Deepam Hospital, Chennai.

Objective:

The course provides students with

- An understanding of clinical research and its scope in drug discovery process
- Hands-on Training on tools related to Clinical Data Management and Pharmacovigilance

Need for the Value-Added Program:

- The under-reporting of adverse drug reactions is the major setback worldwide which may be attributed to the lack of time and report forms. Administration of clinical trials, collection, analysis and coordination of data related to drug side effects play a major role in making legal decisions regarding branded drugs. This course will help the students in developing the skills required to work in the Clinical Research, Clinical Data Management and Pharmacovigilance.

Target Participants:

Class: **III B.Tech. Biotechnology** (2020-24 Batch)

No. of students: **48**

Duration: 4 Days (32 hours)

Tentative Dates: 6th to 9th February 2023

Program Coordinators: Dr. R. Baskaran, Dr. A. Ronaldo Anuf and Mr. Karl Joseph Samuel

Expected Outcome:

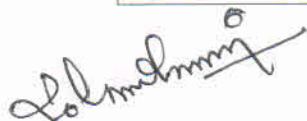
- The student will learn the Practical aspects of important Pharmacovigilance activities as per the global standards.
- The students will acquire the necessary skills and knowledge to work in the Clinical Research Organizations.

PROGRAM SCHEDULE

Day	09:10 AM to 10:50 AM	11:10 AM to 12:50 PM	01:30 PM to 05:30 PM
Day 1	Basic of Clinical Research- Overview	Basics of Clinical Pharmacology	Drug Development Process; Clinical Trial Design and trial Documents
Day 2	Ethics, Guidelines & Regulations; Roles and Responsibilities of CR professional	Overview of CDM; 21CFR part 11-EDC; CDISC Regulations, GCDMP; Protocol review and CRF design;	Database setup, design, and validation; Data entry and validation; Coding and dictionaries; Database lock
Day 3	Good Clinical Practice (GCP)	SAS® Programming.	
Day 4	Pharmacovigilance - Aim, Roles	KPI, Databases	Naranjo Algorithm - PV Prediction

BUDGET

S.No	Category	Particulars	Price (Rs.)	Total (Rs.)
1.	Course Fee	Rs. 1000 per Student inclusive of all taxes	48,000.00	48,000.00
2.	Certificates		800.00	800.00
3.	Miscellaneous		1000.00	1000.00
TOTAL				49,800.00
Cost Per Student: (Rs 49,800/48) = Rs. 1037.50/-				



Program Coordinator(s)


HOD / BT


Principal



DEEPAM HOSPITAL

(DEEPAM HOSPITAL & WELLNESS ENTERPRISES)
(24 Hrs Accident & ICU Care Hospital)

No. 327, Muthurangam Road, West Tambaram, Chennai-600 045.
Phone : 044 - 4397 0201 / 4397 0202 / 83000 17171

30.01.2023

To :
The Principal,
Kamaraj College of Engineering and Technology,
Virudhunagar.

Training Fee - Clinical Research and Pharmacovigilance

Course Details : Four Days Hands on Training on Clinical Research and Pharmacovigilance
Total Hours : 30 hrs
Topics : Clinical Research, Data Management and Pharmacovigilance
Course Fee : Rs.1000 per Student (Inclusive of Taxes)
Total payment : 48,000 (48 Students)
Training Date : 06.02.2023 to 09.02.2023

Accounts Details

A/C Name : Deepam Hospital and Wellness Enterprises
A/C No. : 3218055001145
IFSC Code : ICIC 0003218
Bank : ICICI Bank
Branch : Urapakkam



For Emergency Care - Contact : 83000 17171

Deepam Home Health Care Services - Contact : 9150065122



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DEPARTMENT OF BIOTECHNOLOGY

CIRCULAR

KAMARAJ/BT/2022-23/VAP-III-BT/

Date: 04-02-2023

The Department of Biotechnology is organizing an **Industry Certified Value Added Program** on “**CLINICAL RESEARCH AND PHARMACOVIGILANCE**” in association with **Deepam Hospital, Chennai**, for **III Year B. Tech Biotechnology Students**. The 4 Days course is scheduled from **06th to 9th February 2023**. The program schedule for Value added program is given below.

Program Schedule

Day	09:10 AM to 10:50 AM	11:10 AM to 12:50 PM	01:30 PM to 05:30 PM
06-02-2023	Basic of Clinical Research- Overview	Basics of Clinical Pharmacology	Drug Development Process; Clinical Trial Design and trial Documents
07-02-2023	Ethics, Guidelines & Regulations; Roles and Responsibilities of CR professional	Overview of CDM; 21CFR part 11-EDC; CDISC Regulations, GCDMP; Protocol review and CRF design;	Database setup, design, and validation; Data entry and validation; Coding and dictionaries; Database lock
08-02-2023	Good Clinical Practice (GCP)	SAS* Programming.	
08-02-2023	Pharmacovigilance – Aim, Roles	KPI, Databases	Naranjo Algorithm – PV Prediction


Program Coordinators


HoD/BT


Principal

Copy to:

1. B. Tech Biotechnology III Year Class
2. BT Faculty Members
3. Office Superintendent
4. To File

Course Code	Course Name	Credits
	CLINICAL RESEARCH AND PHARMACOVIGILANCE	2

Category: Value added Course

a. Preamble

This course provides students

- Comprehensive practical knowledge of the clinical research and drug development processes, regulatory affairs and essential documentations.
- Training on clinical research and pharmacovigilance (PV) related issues.

b. Course Outcomes

After successful completion of the course, the students will be able to

CO.No.	Course Outcome	Knowledge Level
CO1	Explain the regulatory requirements for conducting clinical trial	K2
CO2	Perform appropriate documentational requirements for Clinical trials	K3
CO3	Apply basic concepts of Pharmacovigilance	K3
CO4	Perform ADR reporting, methods and other tools used in Pharmacovigilance	K3
CO5	Analyse the adverse drug reaction and its management	K4

c. Course Syllabus

Total: 30 Hours

CLINICAL RESEARCH

10

Basic of clinical Research including Overview, Basic of Clinical Pharmacology, Drug Development process; Clinical Trial Design and trial Documents; Ethics, Guidelines & Regulations; Roles and Responsibilities of CR professional, Forms Filing.

CLINICAL DATA MANAGEMENT

10

Overview of CDM; 21CFR part 11-EDC; CDISC Regulations, GCDMP; Protocol review and CRF design; Database setup, design, and validation; Data entry and validation; Coding and dictionaries; Database lock. Good Clinical Practice (GCP), SAS® Programming.

PHARMACOVIGILANCE

10

Aim, Roles, KPI, Databases, ICH Guidelines, Global PV Laws & Regulations, Medical coding, ICD-10, Naranjo Algorithm

d. Learning Resources

i. TEXT BOOKS

1. Friedman, Lawrence M., Curt D. Furberg, David L. DeMets, David M. Reboussin, and Christopher B. Granger. *Fundamentals of clinical trials*. springer, 2015.
2. Doan, Thao, Linda Scarazzini, Cheryl Renz, Fabio Lievano, and Mondira Bhattacharya, eds. *Pharmacovigilance: A Practical Approach*. Elsevier Health Sciences, 2018.

ii. REFERENCE BOOKS

1. Huang, Shiew-Mei, Juan JL Lertora, and Arthur J. Atkinson Jr, eds. *Principles of clinical pharmacology*. Academic Press, 2012.
2. Orleans-Lindsay, Justina. *Pharmacovigilance Medical Writing: A Good Practice Guide*. John Wiley & Sons, 2012.

Department of Bioechnology

Sixth BoS Meeting Minutes

Date : 10-03-2023











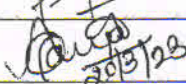
Time : 10.00 AM

Venue : Bioinformatics Laboratory, Dept of Biotechnology, KCET

Link (hybrid mode) :-

The following members were present:

S.No	Name of the Expert	Designation	Capacity
1	Dr. S. Venkatesan	Professor & Head, Department of Petrochemical Technology, Bharathidasan Institute of Technology (BIT) Campus, Tiruchirappalli- 620 024	Anna University Nominee
2	Dr. P. Suresh Kumar	Professor & Head, Department Of Biotechnology, University College Of Engineering, Bharathidasan Institute Of Technology Campus, Tiruchirappalli	Academic Council Nominee
3	Dr. R. Balakrishnaraja	Associate Professor and Head, Department Of Biotechnology, Bannari Amman Institute of Technology, Sathyamangalam	Academic Council Nominee
4	Mr. S. Seshan	Management Representative, The Peninsular Exports Company, Virudhunagar	Industrial Expert
5	Dr. Ilanila I.P.	Assistant Professor, School of Biotechnology, National Institute of Technology Calicut, Kerala	Alumni

Internal faculty Members of BoS			
S.No	Name of the Faculty	Designation	Signature
1	Dr. R. Shyam Kumar	Professor and Head	
2	Dr. R. Baskaran	Associate Professor	
3	Dr. K. Geetha	Associate Professor	
4	Dr. S. Karthikumar	Associate Professor	
5	Mr. S. Manibalan	Assistant Professor	
6	Dr. A. Ronaldo Anuf	Assistant Professor	
7	Dr. D. Pradiba	Assistant Professor	
8	Er. R. Amuthalakshmi	Assistant Professor	
9	Er. K. Chitradevi	Assistant Professor	
10	Er. Karl Joseph Samuel	Assistant Professor	
11	Er. A. Ganga	Assistant Professor	

006.01.00 : Welcome address by HoD

- Dr R Shyam Kumar, Prof and Head, Dept. of BT delivered the welcome address.

006.02.00 : Introduction of BoS members and new Academic Council Nominee

- Dr R Shyam Kumar, Prof and Head, Dept. of BT introduced the members of BoS to each other and to the staff members of the department.

006.03.00 : Approval of 5th BoS Meeting Minutes & Action taken

Item No.	Suggestions of BoS Members in 5 th BoS Meeting	Action Taken
1.	Summer Internship - students can visit any industry/ institute/ other educational organization/ research centre/ entrepreneurship activity	The proposed suggestion was accepted and included

006.05.01 : Changes or corrections in the existing curriculum of R2020 and R2021

Existing	Corrections required and specify the reasons
<u>Course Code & Name & Regulation</u>	Nil
<u>Course Code & Name & Regulation</u>	Nil
<u>Credit Adjustment</u>	Nil
<u>Course Code & Name & Regulation</u>	Nil

006.05.02 : NPTEL Examination results (students performance) and action taken for the students who did not receive the certificates

- The Head of the department presented the results of NPTEL examination performed in the previous semesters and all the BoS experts appreciated the results.
- Dr Venkatesan, Anna University Nominee suggested that the students who have failed should be given another chance to repeat the same NPTEL course again.
- The HoD explained the procedure followed by KCET COE (Controller of Examinations) to the members and the experts accepted it.

006.05.03 : Value Added Courses offered if any

- Mr. S. Seshan enquired about the Management related value added courses (GLP, GMP) offered by the department and he also suggested to include the such courses as it would improve the job oppurtunities
- All the BoS members accepted his suggestion without any concern.
- The BoS co - ordinator sought the ratification of the Value added course on Clinical trials and Pharmacovigilance and all the BoS experts accepted the content without any concern.
- Dr. R. Balakrishnaraja, Academic council nominee suggested to change the title of the Computer Aided Drug Designing (CADD) course and also suggested that the course is not apt for R2021 as it is already included in the curriculum

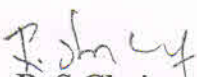
- BoS Coordinator informed about the latest amendments to include the above course in the 1st and 2nd semester. The courses are provided with one credit
- The HoD presented the achievements of students in extracurricular and cocurricular events. The members appreciated the achievements and encouraged for more participations in future.



006.08.00 : Vote of Thanks

- The meeting ended with the Vote of Thanks proposed by Dr.A.Ronaldo Anuf, Assistant Professor, Department of Biotechnology, Kamaraj College of Engineering and Technology, Virudhunagar.


 BoS Coordinator
 (Dr.A.Ronaldo Anuf)


 BoS Chairman
 (Dr.R.Shyam Kumar)
 HoD / BT.



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DEPARTMENT OF BIOTECHNOLOGY

MINUTES OF MEETING TO APPROVE AND RECOMMEND THE VALUE ADDED PROGRAM EXAMINATION FOR CREDIT

Date : 28-04-2023
Time : 01:30 PM to 02:00 PM
Venue : HOD Cabin, Department of Biotechnology

Members Present

1. Dr. R. Shyam Kumar (HOD/BT & Convenor)
2. Dr. A. Ronaldo Anuf (AP/BT & Member)
3. Er. Karl Joseph Samuel (AP/BT & Member)

Agenda

1. Welcome Address – Dr. R. Shyam Kumar.
2. Dissemination of the report of Industry certified value added program on “Clinical Research and Pharmacovigilance” – Dr. A. Ronaldo Anuf.
3. Dissemination of value added program guidelines in R2020 – Er. Karl Joseph Samuel.
4. Dissemination of the report on mode of conduct of examination and evaluation system – Er. Karl Joseph Samuel.
5. Approval of the program conduct and examination evaluation system to issue the credit as per the regulation R2020.
6. Any other items with the approval of convener.

THE HISTORY OF THE CITY OF BOSTON

FROM THE FIRST SETTLEMENT
TO THE PRESENT TIME

BY
NATHANIEL PHIPPS

IN TWO VOLUMES.

LONDON: PRINTED BY RICHARD CLAY AND COMPANY, LTD., BUNGAY, SUFFOLK.
1931.

✓



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DEPARTMENT OF BIOTECHNOLOGY

MINUTES OF MEETING TO APPROVE AND RECOMMEND THE

VALUE ADDED PROGRAM EXAMINATION FOR CREDIT

Item No	Agenda	Discussion and Resolution
1.	Welcome Address	Dr. R. Shyam Kumar, Head and convenor of the meeting welcomed the gathering and gave a brief introduction about the purpose and agenda of the meeting
2.	Dissemination of the report of value added program	Dr. A. Ronaldo Anuf, AP/BT and one of the coordinators of the event explained the objective, need, target participant, duration and expected outcome of the program “Industry certified value added program on Clinical Research and Pharmacovigilance” organized from 06 February 2023 to 09 February 2023. The program was conducted for 3 rd year B. Tech Biotechnology students as per the regulation R2020. Resource persons from Deepam Hospital, Chennai provided technical training to the students during the program. Detailed event report is attached.
3.	Dissemination of the Value added Program Guidelines in R2020	Er. Karl Joseph Samuel, AP/BT and one of the coordinators of the event disseminated the points discussed in the BOS Meeting. The syllabus for Value added course “Clinical Research and Pharmacovigilance” was ratified at the meeting.

Item No	Agenda	Discussion and Resolution
4.	Dissemination of the report on mode of conduct of the examination and evaluation system	Er. Karl Joseph Samuel, AP/BT explained the mode of conduct of examination. During the course of program, the students were assessed as internal assessment (for 100 Marks). Later a main exam covering 50 MCQs from Clinical Research and Pharmacovigilance was conducted in online mode with proper invigilation. The marks scored by each students were presented to the committee members for the approval
5.	Approval of the Program conduct and examination evaluation system to issue credit as per regulation R2020	The three member committee (Dr. R. Shyam Kumar, Dr. A. Ronaldo Anuf and Er. Karl Joseph Samuel) was formed to scrutinize the value added program exam results to approve and recommend for credit. The committee members verified the results and forwarded to Controller of Examination through Dean Academics to consider for 2 Credits.
6.	Any other items with the approval of convener	Hence, no members raised any further clarification, the meeting was end and the reports were forwarded for further process.

Er. Karl Joseph Samuel,
AP/BT, Member

Dr. A. Ronaldo Anuf,
AP/BT, Member

Dr. R. Shyam Kumar
HOD/BT & Convener



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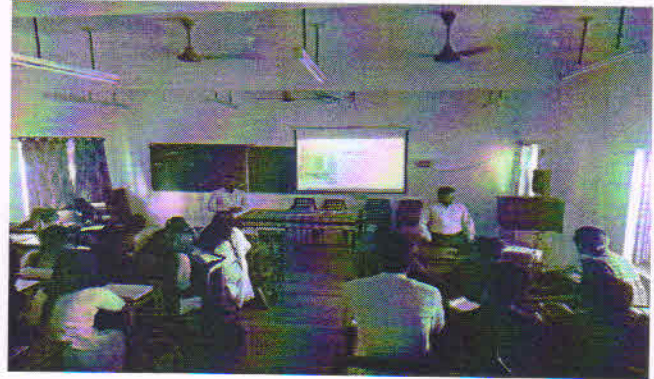
In association with

Deepam Hospital, Chennai.

06-02-2023 to 09-02-2023

PHOTOS

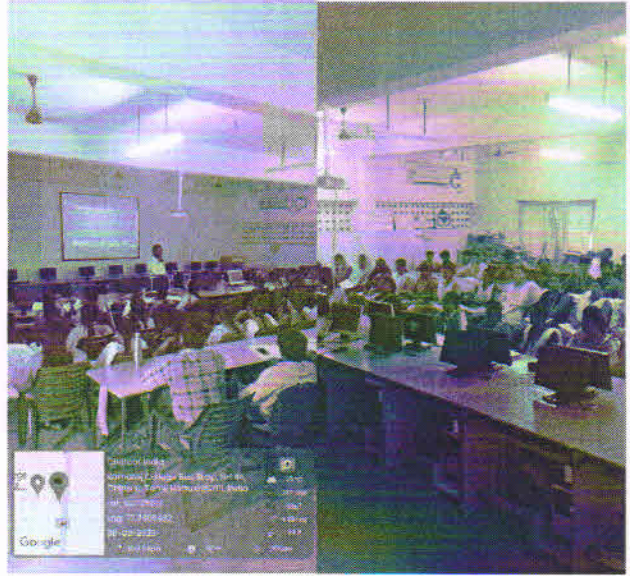
DAY 1 (06-02-2023)



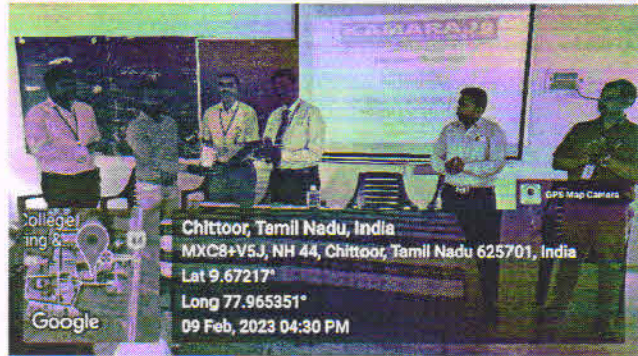
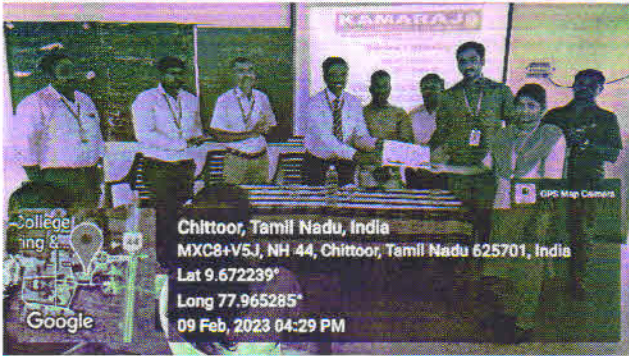
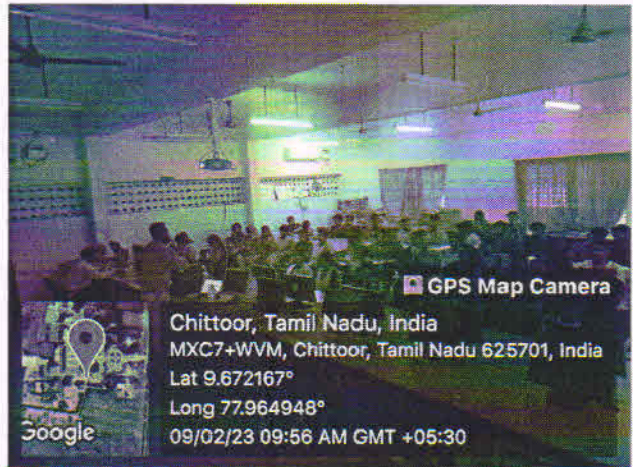
DAY 2 (07-02-2023)




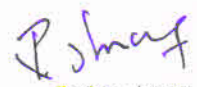
DAY 3 (08-02-2023)



DAY 4 (09-02-2023)




Program Coordinator(s)


HOD / BT

SI.NO: DAMS/2022/300 / KCET / 20UBT001



CARE

iMedi career



**GANDHI
FOUNDATION**

DEEPAM ACADEMY OF MEDICAL SCIENCES

Has Conferred upon

**SRIVIDHYA R., Dept of Biotechnology, Kamaraj College of Engg & Tech, VNR
(III-BT)**

For having completed the training both practical and theory in

CLINICAL RESEARCH AND PHARMACOVIGILANCE

From **06-02-2023** To **09-02-2023** (32 hours)



Head of the Department



SI.NO: DAMS/2022/300/KCET/20UBT002



CARE

iJedi career



GANDHI
FOUNDATION

DEEPAM ACADEMY OF MEDICAL SCIENCES

Has Conferred upon

SUDHARSAN.M (III-BT), Dept of Biotechnology, Kamaraj College of Engg & Tech, Vnr

For having completed the training both practical and theory in

CLINICAL RESEARCH AND PHARMACOVIGILANCE

From 06-02-2023 To 09-02-2023 (32 hours)

Head of the Department



SI.NO: DAMS/2022/300 / KCET / 20UBT 003



**DEEPAM
HOSPITALS
CHENNAI**



CARE

iMedi career



**GANDHI
FOUNDATION**

DEEPAM ACADEMY OF MEDICAL SCIENCES

Has Conferred upon

JEFFRY DANIEL D (III - BT) , Dept of Bpotechnology, Kamaraj college of Engg & Tech , VNR

For having completed the training both practical and theory in

CLINICAL RESEARCH AND PHARMA COVIGILANCE

From 06.02.2023 To 09.02.2023 (



Head of the Department

SI.NO: DAMS/2022/300 / KCET/20UBT004



Medi career



GANDHI
FOUNDATION

DEEPAM ACADEMY OF MEDICAL SCIENCES

Has Conferred upon

GIRITHARAN.S (III - BT) , Dept of Biotechnology , Kamaraj college of Engg & Tech , VNR

For having completed the training both practical and theory in

CLINICAL RESEARCH AND PHARMACOVIGILANCE

From 06-02-2023 To 09-02-2023 (32 hours)



Head of the Department



SI.NO: DAMS/2022/300 / KCET/20UBT005



iMedi career



GANDHI FOUNDATION

DEEPAM ACADEMY OF MEDICAL SCIENCES

Has Conferred upon

SIVA SANKARI.K (III-BT), Dept of Biotechnology, Kamaraj college of Engg & Tech, VNR

For having completed the training both practical and theory in

CLINICAL RESEARCH AND PHARMACOVIGILANCE

From 06-02-2023 To 09-02-2023 (32 hours)



Head of the Department

SI.NO: DAMS/2022/300/KCET/20UBT006



Medi career



GANDHI
FOUNDATION

DEEPAM ACADEMY OF MEDICAL SCIENCES

Has Conferred upon

THILSATH MEERAL-S (III-BT), Dept of Biotechnology, Kamaraj college of Engg & Tech, VNR
.....

For having completed the training both practical and theory in

CLINICAL RESEARCH AND PHARMA COVIGILANCE
.....

From 06-02-2023 To 09-02-2023
.....



Head of the Department



SI.NO: DAMS/2022/300 / KCET/20UBT008



Medi career



GANDHI
FOUNDATION

DEEPAM ACADEMY OF MEDICAL SCIENCES

Has Conferred upon

FAHEEMA THAHASEEN.A (III-BT), Dept of Biotechnology, Kamaraj College of Engg & Tech, VNR

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CLINICAL RESEARCH AND PHARMACOVIGILANCE

From 06-02-2023 To 09-02-2023



Head of the Department



Sl.NO: DAMS/2022/300 / KCET / 20UBT 009



Medi career



GANDHI
FOUNDATION

DEEPAM ACADEMY OF MEDICAL SCIENCES

Has Conferred upon

SAND OSHMANI . R (III - BT) , Dept of Biotechnology , Kamaraj college of Engg & Tech, VNR

For having completed the training both practical and theory in

CLINICAL RESEARCH AND PHARMACOVIGILANCE

From 06-02-2023 To 09-02-2023



Head of the Department



Sl.NO: DAMS/2022/300 / KCE T/200BT010



Medi career



GANDHI FOUNDATION

DEEPAM ACADEMY OF MEDICAL SCIENCES

Has Conferred upon

RAVINA.R (III - BT), Dept of Biotechnology, Kamaraj College of Engg & Tech, VNR

For having completed the training both practical and theory in

CLINICAL RESEARCH AND PHARMACOVIGILANCE

From 06-02-2023 To 09-02-2023



Head of the Department



SI.NO: DAMS/2022/300/KCET / 20VBTO11



iMedi career



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From 06-02-2023 To 09-02-2023



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From 06-02-2023. To 09-02-2023
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.....
CLINICAL RESEARCH AND PHARMACOVIGILANCE
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From ~~06-02-2023~~ To 09-02-2023



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CLINICAL RESEARCH AND PHARMA COVIGILANCE

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CLINICAL RESEARCH AND PHARMA COMPLIANCE

From 06.02.2023.. To 09.02.2023



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From 06-02-2023 To 09-02-2023



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From 06.02.2023 To 09-02-2023



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From 06-02-2023 To 09-02-2023



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From 06-02-2023 To 09-02-2023



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GOKULNATH S - III, Dept. of Biotechnology, Kamaraj College of Engg. & Tech, VNR

For having completed the training both practical and theory in

CHEMICAL RESEARCH AND PHARMACOVIGILANCE

From 06.02.2023 To 01.02.2023



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CLINICAL RESEARCH AND PHARMACOVIGILANCE

From 02-02-2023 To 09-02-2023



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VARSHA.G.V.-IV, Dept. of Biotechnology, Kamaraj College of Engg & Tech, VNR

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From 06-02-2023 To 09-02-2023



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From 06.02.2023 To 09.02.2023



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From 06-02-2023 To 09-02-2023



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From 06-02-2023 To 09-02-2023



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From 06-02-2023 To 09-02-2023



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For having completed the training both practical and theory in

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From 06-02-2023 To 01-02-2023



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SI.NO: DAMS/2022/300/KCET/2008T034



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From 06-02-2023 To 09-02-2023



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LAMIYA BANU. M-III, Dept. of Biotechnology, Kamaraj College of Engg. & Tech, VNR

For having completed the training both practical and theory in

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From 06.02.2023 To 07.02.2023



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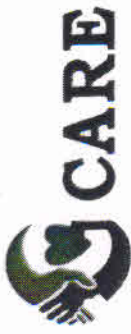
From 06-02-2023 To 07-02-2023



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From 06-02-2023 To 09-02-2023



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GOWSALYA.K.K-iii, Dept of Biotechnology, Kamaraj College of Engg & Tech, VNR

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From 06.02.2023. To 09.02.2023



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VINODHINI R-III, Dept of Biotechnology, Kamaraj College of Engg & Tech, VNR

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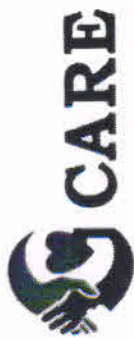
From 06-02-2023 To 09-02-2023



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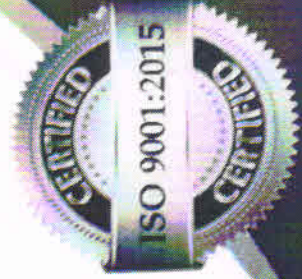
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S.P.G.C. Nagar, K.Vellakulam - 625 701 (Near VIRUDHUNAGAR).

DEPARTMENT OF BIOTECHNOLOGY

CIRCULAR

KAMARAJ/BT/2022-23/VAP-III-BT/

Date: 18-04-2023

The online assessment examination for the value-added programme on “**Clinical Research and Pharmacovigilance**” is scheduled for 20 April 2023 from 1.45 PM to 3.15 PM.

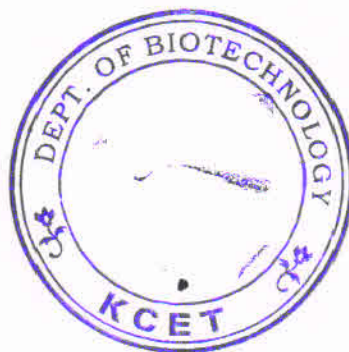
The following instructions are to be followed

1. All students should take the examination by using a laptop
2. Join the link 10 minutes before the commencement of the examination
3. Students who attended the VAP programme are only eligible to take the test.
4. The test will be conducted in proctored mode
5. Question paper pattern MCQ 50. (50 × 1 = 50 Marks)

Test Link:

<https://bit.ly/kcetiiibtvap2223>


Program Coordinators




HoD/BT

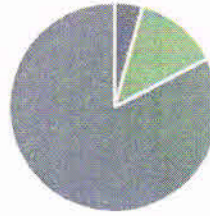
Copy to:

1. B. Tech Biotechnology III Year Class
2. BT Faculty Members
3. Office Superintendent
4. To File

4. **What is placebo?** (1 point)

83% of respondents (38 of 46) answered this question correctly.

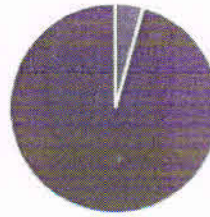
- a) The subjects do not know whi... 2
- b) Patients injected with placeb... 6
- c) Fake treatment 38 ✓
- d) Signed document of the recr... 0



5. **What is informed consent in a clinical trial?** (1 point)

96% of respondents (44 of 46) answered this question correctly.

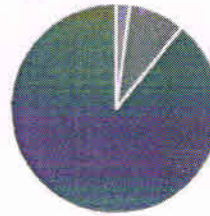
- a) The subjects do not know whi... 0
- b) Patients injected with placeb... 0
- c) Fake treatment 2
- d) Signed document of the recr... 44 ✓



6. **Which one of the following is the last step of a clinical trial process?** (1 point)

89% of respondents (41 of 46) answered this question correctly.

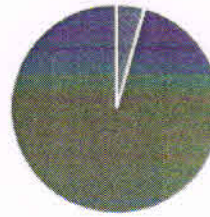
- a) Investigator selection 0
- b) Patient recruitment 1
- c) Statistical Analysis 4
- d) Data filed and registration 41 ✓



7. **How many people will be selected for phase I trial?** (1 point)

96% of respondents (44 of 46) answered this question correctly.

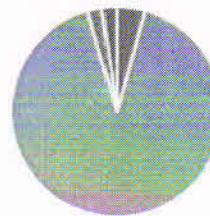
- a) The whole market will be und... 0
- b) 300-3000 people 0
- c) 20-300 people 2
- d) 20-50 people 44 ✓



8. **Which of the following country is the most attractive location to perform clinical trials outside the United States?** (1 point)

91% of respondents (42 of 46) answered this question correctly.

- a) India 2
- b) China 42 ✓
- c) United Kingdom 1
- d) Germany 1



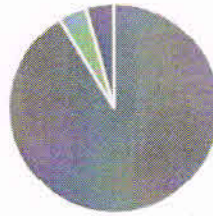
Handwritten signature and text:
P. Singh
Coordinators

Handwritten signature and text:
P. Singh
HOD/Br

9. In which phase pharmacodynamics and pharmacokinetics of a drug are studied? (1 point)

91% of respondents (42 of 46) answered this question correctly.

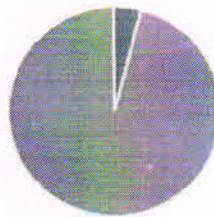
- a) Phase I 42 ✓
- b) Phase II 2
- c) Phase III 0
- d) Phase IV 2



10. What is the full form of SAD? (1 point)

96% of respondents (44 of 46) answered this question correctly.

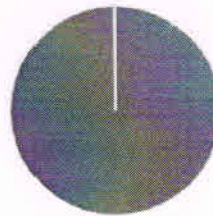
- a) Secure Assessing dose 2
- b) Single Ascending Dose 44 ✓
- c) Sodium Ascending Dose 0
- d) Single Amount Dose 0



11. What is the full form of MAD? (1 point)

100% of respondents (46 of 46) answered this question correctly.

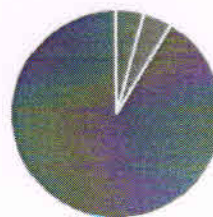
- a) Multiple Ascending Dose 46 ✓
- b) Managing Abnormalities Dose 0
- c) Managing absorption dose 0
- d) Managing Assimilation Dose 0



12. Which of the trial phase is for pharmacovigilance? (1 point)

91% of respondents (41 of 45) answered this question correctly.

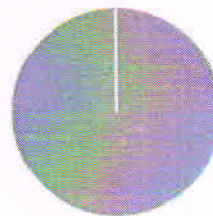
- a) Phase I 2
- b) Phase II 0
- c) Phase III 2
- d) Phase IV 41 ✓



13. What is GCP? (1 point)

100% of respondents (46 of 46) answered this question correctly.

- a) Good cooperation project 0
- b) Good clinical practice 46 ✓
- c) Good cleanliness practice 0
- d) Good Constructor provider 0



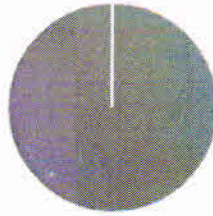
Handwritten notes:
A diagram with arrows pointing to 'Phase I', 'Phase II', and 'Phase III'.
Text: "Coordinator's handling"

Handwritten signature:
P. Sharma
HOD/BT

14. GCP include protection of Human rights as a subject in a clinical trial. (1 point)

100% of respondents (46 of 46) answered this question correctly.

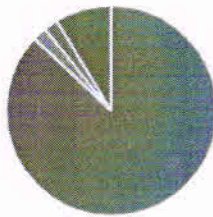
- a) True 46 ✓
- b) False 0



15. What does the symbol Rx mean? (1 point)

87% of respondents (40 of 46) answered this question correctly.

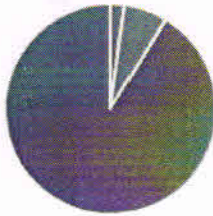
- a) To take 40 ✓
- b) Should date 1
- c) How to take 1
- d) What to take 4



16. What does the abbreviation o.d? means on a prescription? (1 point)

91% of respondents (42 of 46) answered this question correctly.

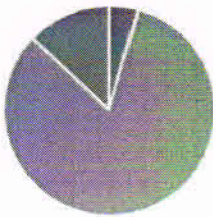
- a) Name of medicine 1
- b) How to take the medicine 0
- c) Quantity to be dispensed 3
- d) Once daily 42 ✓



17. How many diagnosis and CPT codes are reported on the ambulatory care records on the examinations? (1 point)

83% of respondents (38 of 46) answered this question correctly.

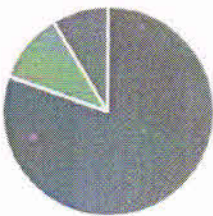
- a) 4 diagnosis, as many CPT pro... 2
- b) 4 diagnosis, 4 CPT procedure ... 38 ✓
- c) As many codes as necessary i... 6



18. A patient undergoes a colonoscopy for possible polyp removal. By hot biopsy forceps, a polyp is removed from the descending colon, and by snare technique, a polyp is removed further up just into the transverse colon. What CPT code(s) are reported by the FACILITY? (1 point)

80% of respondents (37 of 46) answered this question correctly.

- a.) 45385, 45384-59 37 ✓
- b.) 45384, 45385-51 5
- c.) 45385 4
- d.) 45384 0



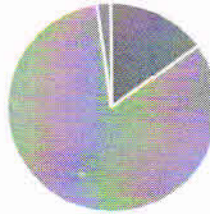
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RJA
Coordinator

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HOB/BT

19. For question #2 what code (s) would be reported for the SURGEON? (1 point)

15% of respondents (7 of 46) answered this question correctly.

- a.) 45385, 45384-59 7 ✓
- b.) 45385, 45384-51 38
- c.) 45385 1
- d.) 45384 0

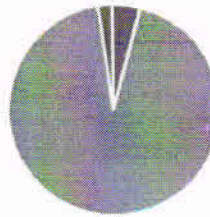


20. Double osteotomy bunionectomy to correct severe hallux valgus of the left first metatarsal with 0.062 K wire fixation and application of cast. (1 point)

(1 point)

93% of respondents (43 of 46) answered this question correctly.

- a.) 28296-TA 2
- b.) 28299-TA 43 ✓
- c.) 28296-TA, 29425-TA 0
- d.) 28299-LT 1

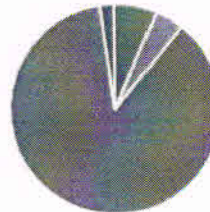


21. Esophagogastroduodenoscopy with dilation of the esophagus over a guide wire at same operative episode. (1 point)

(1 point)

87% of respondents (40 of 46) answered this question correctly.

- a.) 43453, 43235-59 3
- b.) 43226, 43235-59 2
- c.) 43248 40 ✓
- d.) 43456, 43235 1

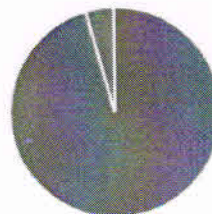


22. Excision of 6-cm inclusion cyst of left neck located below the fascia, entire dissection of tumor from the subfascia; closure of deep fascia with 3-0 Vicryl; skin closed with 4-0 Maxon. Steri-strips were applied. (1 point)

(1 point)

96% of respondents (44 of 46) answered this question correctly.

- a.) 21556 44 ✓
- b.) 11426, 12042-59 0
- c.) 11426 2
- d.) 21557 0



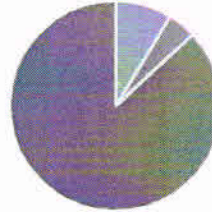
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23. A patient with thoracic vertebral fractures of the spine presents for a percutaneous vertebroplasty. A needle is inserted through the right pedicle of the T7 and T8 vertebral body defects and methyl methacrylate is injected. The procedure was done under fluoroscopic guidance. What codes are reported for the facility? (1 point)

87% of respondents (40 of 46) answered this question correctly.

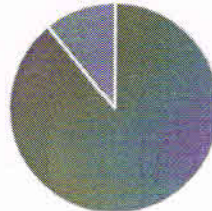
- a.) 22305, 76013-TC 0
- b.) 22325, 76012-TC 4
- c.) 22305, 76012-TC 2
- d.) 22520, 22522, 76012-TC 40 ✓



24. Supervision and interpretation (professional component) for one view study of the ankle provided by the physician. (1 point)

89% of respondents (41 of 46) answered this question correctly.

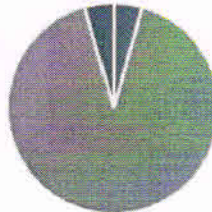
- a.) 73600-52-26 41 ✓
- b.) 73600 5
- c.) 76499-26 0



25. Laboratory components of calcium (82310), carbon dioxide (82374), chloride (82435), creatinine (82565), glucose (82947), potassium (84132), sodium (84295), and nitrogen-BUN (84520) compose what panel? (1 point)

91% of respondents (42 of 46) answered this question correctly.

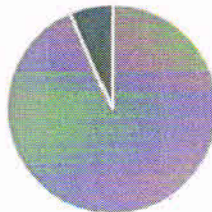
- a.) No panel, code all as individu... 2
- b.) 80048, basic metabolic panel 42 ✓
- c.) 80050, general health panel 0
- d.) 80051, electrolyte panel 2



26. A patient complains of severe lower back and leg pain, which are not responding to conservative treatment. A lumbar caudal injection is given with three injections at the left L4-L5 level for pain relief. (1 point)

93% of respondents (43 of 46) answered this question correctly.

- a.) 62289-LT 0
- b.) 62311-LT 43 ✓
- c.) 62273-LT 0
- d.) 62311-LT, 62311-LT, 62311-LT 3



Handwritten notes:
 F-16
 Coordination
 1/10/2017

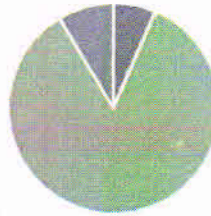
Handwritten notes:
 P. Shrestha
 1/10/2017

32. **Critical care given for less than 30 minutes total duration on a given date should be reported as:**

(1 point)

9% of respondents (4 of 46) answered this question correctly.

- a.) 99291 3
- b.) The appropriate evaluation a... 39
- c.) 99285 4 ✓
- d.) 99499 0

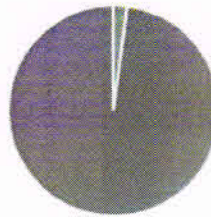


33. **Strabismus surgery. Recession of medial rectus muscle of left eye; strabismus surgery on superior oblique muscle of right eye.**

(1 point)

98% of respondents (45 of 46) answered this question correctly.

- a.) 67312-LT 0
- b.) 67311-LT-51 1
- c.) 67311-LT, 67318-LT 45 ✓

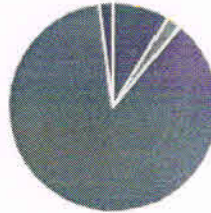


34. **The patient undergoes a right endoscopic total ethmoidectomy, septoplasty with submucous resection.**

(1 point)

87% of respondents (40 of 46) answered this question correctly.

- a.) 31255-RT, 31256-RT 4
- b.) 31201-RT, 31020-RT 1
- c.) 30520-RT, 31255-RT 40 ✓
- d.) 31255-RT 1

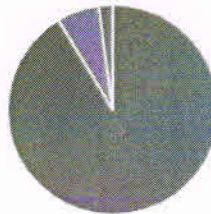



35. **A patient has several calculi of the right and left ureter. A laparoscopic surgical ureterolithotomy is performed and 2 calculi are taken from the left side, 3 from the right.**

(1 point)

91% of respondents (42 of 46) answered this question correctly.

- a.) 50945-50 42 ✓
- b.) 50945-LT-RT 3
- c.) 50945-LT, 50945-LT, 50945-R... 1



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 Coordinators

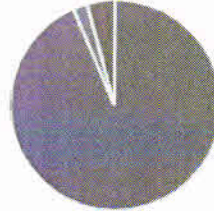
Handwritten notes:
 P. Singh
 HOD/BT

36. Which of the following muscular valve controls the flow of digestive juice from the hepatopancreatic duct to the duodenum?

(1 point)

93% of respondents (43 of 46) answered this question correctly.

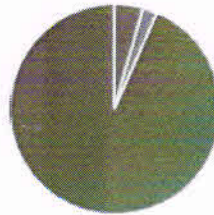
- (a) Sphincter of Oddi 43 ✓
- (b) Semilunar valve 0
- (c) Ileocaecal valve 1
- (d) Pyloric sphincter 2



37. Which of the following is present on the surface of intestinal epithelial cells? (1 point)

93% of respondents (42 of 45) answered this question correctly.

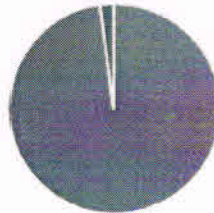
- (a) Zymogen granules 2
- (b) Pinocytic vesicles 1
- (c) Phagocytic vesicles 0
- (d) Microvilli 42 ✓



38. Lungs are enclosed within (1 point)

98% of respondents (45 of 46) answered this question correctly.

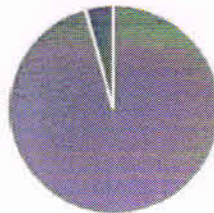
- (a) Perichondrium 0
- (b) Periosteum 0
- (c) Pleural membrane 45 ✓
- (d) Pericardium 1



39. The maximum amount of urea is present in (1 point)

96% of respondents (44 of 46) answered this question correctly.

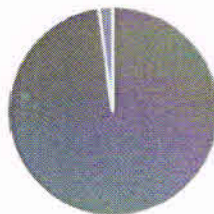
- (a) Dorsal Aorta 0
- (b) Hepatic Vein 44 ✓
- (c) Renal Vein 2
- (d) Hepatic Portal Vein 0



40. Which of the following organs is known as the "graveyard" of RBCs? (1 point)

98% of respondents (45 of 46) answered this question correctly.

- (a) Spleen 45 ✓
- (b) Kidney 1
- (c) Liver 0
- (d) Gall bladder 0



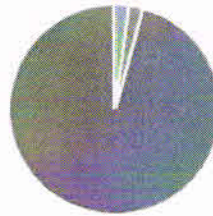
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 Coordinators

Handwritten notes:
 P. 1/10/17
 HoD / BT

41. Which of the following organs contains the 'Bundle of His'? (1 point)

96% of respondents (44 of 46) answered this question correctly.

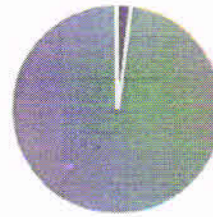
- (a) Pancreas 0
- (b) Brain 1
- (c) Kidney 1
- (d) Heart 44 ✓



42. Heartbeat originates from the (1 point)

98% of respondents (45 of 46) answered this question correctly.

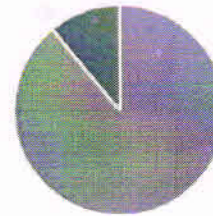
- (a) papillary muscles 1
- (b) SA node 45 ✓
- (c) AV node 0
- (d) Purkinje fibres 0



43. Which of the following features is common to both humans and adult frogs? (1 point)

89% of respondents (41 of 46) answered this question correctly.

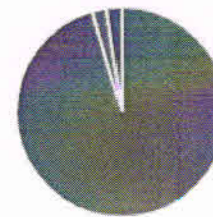
- (a) Internal fertilization 0
- (b) Ureotelic mode of excretion 41 ✓
- (c) Nucleated RBCs 0
- (d) Four chambered heart 5



44. The basic functional unit of a human kidney is known as (1 point)

96% of respondents (44 of 46) answered this question correctly.

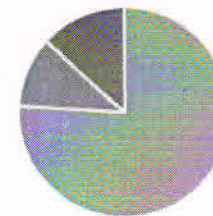
- (a) Nephron 44 ✓
- (b) Pyramid 0
- (c) Henle's loop nephron 1
- (d) Nephridia 1



45. Single uriniferous tubule does not contain (1 point)

76% of respondents (35 of 46) answered this question correctly.

- (a) Loop of Henle 0
- (b) Collecting duct 35 ✓
- (c) Distal convoluted tubule 5
- (d) Bowman's capsule 6

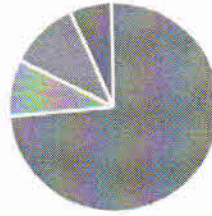


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Coordinators

R. Shree
HoD/BT

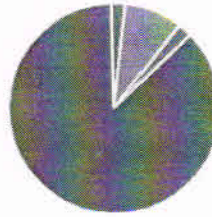
46. Which of the following joints is immovable? (1 point)
74% of respondents (34 of 46) answered this question correctly.

- (a) Fibrous joint 34 ✓
- (b) Synovial joint 4
- (c) Cartilaginous joints 5
- (d) Ball and Socket joint 3



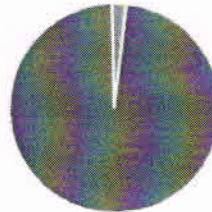
47. The middle portion of the human sperm contains (1 point)
87% of respondents (40 of 46) answered this question correctly.

- (a) Nucleus 1
- (b) Proteins 4
- (c) Centriole 1
- (d) Mitochondria 40 ✓



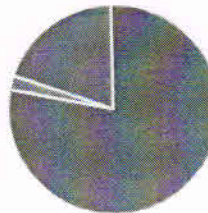
48. Which of the following is the correctly matched pair of an organ and muscles present in the organ? (1 point)
98% of respondents (45 of 46) answered this question correctly.

- (a) Intestine – striated and invol... 0
- (b) Upper arm – smooth muscle ... 1
- (c) Heart – involuntary and unstr... 0
- (d) Thigh – striated and voluntary 45 ✓



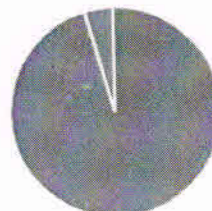
49. Cartilage at the end of long bones is (1 point)
78% of respondents (36 of 46) answered this question correctly.


- (a) Calcified cartilage 36 ✓
- (b) Fibrous cartilage 1
- (c) Hyaline cartilage 9
- (d) Elastic cartilage 0



50. A deltoid ridge is present in (1 point)
96% of respondents (44 of 46) answered this question correctly.

- (a) Humerus 44 ✓
- (b) Femur 0
- (c) Radius 2
- (d) Ulna 0



Handwritten notes:

 The hand is a **Coordinator**

Handwritten signature:
 P. Singh
 HOD/BT

Department of Biotechnology

Value Added Course on "Clinical Research and Pharmacovigilance"

Attendance

Roll Number	Register Number	Student Name	06-02-2023		07-02-2023		08-02-2023		09-02-2023		Total	Attendance %
			FN	AN	FN	AN	FN	AN	FN	AN		
20UBT001	920420UBT001	SRIDIVYA.R	4	4	4	4	4	4	4	4	32	100.00
20UBT002	920420UBT002	SUDHARSAN.M	0	0	4	4	4	4	4	4	24	75.00
20UBT003	920420UBT003	JEFFRY DANIEL.D	4	4	4	4	4	4	4	4	32	100.00
20UBT004	920420UBT004	GIRITHARAN.S	4	4	4	4	4	4	4	4	32	100.00
20UBT005	920420UBT005	SIVA SANKARI.K	4	4	4	4	4	4	4	4	32	100.00
20UBT006	920420UBT006	THILSATH MEERAL.S	4	4	4	4	4	4	4	4	32	100.00
20UBT007	920420UBT007	GOBIKA.G	4	4	4	4	0	0	0	0	16	50.00
20UBT008	920420UBT008	FAHEEMA THAHASEEN.A	4	4	4	4	4	4	4	4	32	100.00
20UBT009	920420UBT009	SANDOSHMANI.R	4	4	4	4	4	4	4	4	32	100.00
20UBT010	920420UBT010	RAVINA.R	4	4	4	4	4	4	4	4	32	100.00
20UBT011	920420UBT011	MOULI MONISHA.V	4	4	4	4	4	4	4	4	32	100.00
20UBT012	920420UBT012	ARAVIND.R	4	4	4	4	4	4	4	4	32	100.00
20UBT013	920420UBT013	AKASH DEV.M.S	4	4	4	4	4	4	4	4	32	100.00
20UBT014	920420UBT014	KEERTHI VASAN.V	4	4	4	4	4	4	4	4	32	100.00
20UBT015	920420UBT015	DINESH.R	0	0	4	4	4	4	4	4	24	75.00
20UBT016	920420UBT016	BENITA MARGARET.L	4	4	4	4	4	4	4	4	32	100.00
20UBT017	920420UBT017	JASMINE KILDA.L	4	4	4	4	4	4	4	4	32	100.00
20UBT018	920420UBT018	MADHUMITHA.K	4	4	4	4	4	4	4	4	32	100.00
20UBT019	920420UBT019	DEEJITH NAA TIYAAL.M.S	4	4	4	4	4	4	4	4	32	100.00
20UBT020	920420UBT020	KAMALI.S	4	4	4	4	4	4	4	4	32	100.00
20UBT021	920420UBT021	SINDHUJA.S	4	4	4	4	4	4	4	4	32	100.00
20UBT022	920420UBT022	NITHYASREE.A	4	4	4	4	4	4	4	4	32	100.00
20UBT023	920420UBT023	VARSHINIRAJI.P	4	4	4	4	4	4	4	4	32	100.00
20UBT024	920420UBT024	ABINAYA.J	4	4	4	4	4	4	4	4	32	100.00
20UBT025	920420UBT025	SAIBHAVADHARAN.I.B	4	4	4	4	4	4	4	4	32	100.00
20UBT026	920420UBT026	GOKULNATH.S	4	4	4	4	4	4	4	4	32	100.00



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 S.P.G.Chidambara Nader - C.Nagammal Campus
 S.P.G.C. Nagar, K.Vellakulam - 625 701 (Near VIRUDHUNAGAR).

Department of Biotechnology

Value Added Course on "Clinical Research and Pharmacovigilance"

Attendance

Roll Number	Register Number	Student Name	06-02-2023		07-02-2023		08-02-2023		09-02-2023		Total	Attendance %
			FN	AN	FN	AN	FN	AN	FN	AN		
20UBT027	920420UBT027	SUBHIKSHA.S	4	4	4	4	4	4	4	4	32	100.00
20UBT028	920420UBT028	VARSHA.G.V	4	4	4	4	4	4	4	4	32	100.00
20UBT029	920420UBT029	RINISHA.R	4	4	4	4	4	4	4	4	32	100.00
20UBT030	920420UBT030	NARASINGAM.R	4	4	4	4	4	4	4	4	32	100.00
20UBT031	920420UBT031	JOHN PAUL HUDSON.S	4	4	4	4	4	4	4	4	32	100.00
20UBT032	920420UBT032	JEGADEESH.M	4	4	4	4	4	4	4	4	32	100.00
20UBT033	920420UBT033	VAIRAMUTHU.P	4	4	4	4	4	4	4	4	32	100.00
20UBT034	920420UBT034	VAISHAALI.A.M	4	4	4	4	4	4	4	4	32	100.00
20UBT035	920420UBT035	YOGASRI.M	4	4	4	4	4	4	4	4	32	100.00
20UBT036	920420UBT036	BOOJITHA.E	4	4	4	4	4	4	4	4	32	100.00
20UBT037	920420UBT037	LAMIYA BANU.M	4	4	4	4	4	4	4	4	32	100.00
20UBT038	920420UBT038	VARSHA.E	4	4	4	4	4	4	4	4	32	100.00
20UBT039	920420UBT039	SAKTHI SUREGA.P	4	4	4	4	4	4	4	4	32	100.00
20UBT040	920420UBT040	GOWSALYA.K	4	4	4	4	4	4	4	4	32	100.00
20UBT041	920420UBT041	MINUSHA.S	0	0	0	0	0	0	4	4	8	25.00
20UBT042	920420UBT042	VINODHINI.R	4	4	4	4	4	4	4	4	32	100.00
20UBT043	920420UBT043	CERLICLADIYA.P	4	4	4	4	4	4	4	4	32	100.00
20UBT044	920420UBT044	SHANKAR GANESH.M.V	4	4	4	4	4	4	4	4	32	100.00
20UBT045	920420UBT045	HARSINI.S	4	4	4	4	4	4	4	4	32	100.00
20UBT046	920420UBT046	PRASANNA VENGATESH.V	4	4	4	4	4	4	4	4	32	100.00
20UBT047	920420UBT047	AAEIF HUSSAIN	4	4	0	0	0	0	0	0	8	25.00
20UBT049	920120UBT049	NITHYASHREE.S.R	4	4	4	4	4	4	4	4	32	100.00

[Signature]

Coordinators

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HOD / BT



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 S.P.G. Chidambara Nagar - C. Nagermet Campus
 S.P.G.C Nagar, K. Vellakulam - 625 701, (Near VERUDHUNAGAR).

DEPARTMENT OF BIOTECHNOLOGY

Industry Certified Value-Added Course

On

CLINICAL RESEARCH AND PHARMACOVIGILANCE

S. No	Roll No	Reg No	Name	06-02-2023			07-02-2023			08-02-2023			09-02-2023		
				1	2	4	1	2	3	1	2	3	1	2	3
37	20UBT037	920420UBT037	LAMIYA BANU.M	M.L.K.	M.L.K.	M.L.K.	M.L.K.	M.L.K.	M.L.K.	M.L.K.	M.L.K.	M.L.K.	M.L.K.	M.L.K.	M.L.K.
38	20UBT038	920420UBT038	VARSHA.E	S.D.	S.D.	S.D.	S.D.	S.D.	S.D.	S.D.	S.D.	S.D.	S.D.	S.D.	S.D.
39	20UBT039	920420UBT039	SAKTHI SUREGA.P	P.P.	P.P.	P.P.	P.P.	P.P.	P.P.	P.P.	P.P.	P.P.	P.P.	P.P.	P.P.
40	20UBT040	920420UBT040	GOWSALYA.K	G.	G.	G.	G.	G.	G.	G.	G.	G.	G.	G.	G.
41	20UBT041	920420UBT041	MINUSHA.S	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB
42	20UBT042	920420UBT042	VINODHINI.R	R.V.	R.V.	R.V.	R.V.	R.V.	R.V.	R.V.	R.V.	R.V.	R.V.	R.V.	R.V.
43	20UBT043	920420UBT043	CERLICLADIYA.P	C.	C.	C.	C.	C.	C.	C.	C.	C.	C.	C.	C.
44	20UBT044	920420UBT044	SHANKAR GANESH.M.V	M.V.	M.V.	M.V.	M.V.	M.V.	M.V.	M.V.	M.V.	M.V.	M.V.	M.V.	M.V.
45	20UBT045	920420UBT045	HARSINI.S	H.	H.	H.	H.	H.	H.	H.	H.	H.	H.	H.	H.
46	20UBT046	920420UBT046	PRASANNA VENGATESH.V	P.V.	P.V.	P.V.	P.V.	P.V.	P.V.	P.V.	P.V.	P.V.	P.V.	P.V.	P.V.
47	20UBT047	920420UBT047	AASIF HUSSAIN	A.H.	A.H.	A.H.	A.H.	A.H.	A.H.	A.H.	A.H.	A.H.	A.H.	A.H.	A.H.
48	20UBT049	920420UBT049	NITHYASHREE.S.R	N.S.R.	N.S.R.	N.S.R.	N.S.R.	N.S.R.	N.S.R.	N.S.R.	N.S.R.	N.S.R.	N.S.R.	N.S.R.	N.S.R.

[Handwritten Signature]
 Coordinator

[Handwritten Signature]
 HOD/BI

Review: Value Added Program Examination - Clinical Trials and Pharmacovigilance (2022-23)

Respondent

1

VARSHINI RAJ.P(BT)

26:25

Time to complete

38/50

Points

✓ **Correct** 1/1 Points

1 / 1 pt
Auto-graded

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- b) Good clinical practice ✓
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- b.) 73600
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- b.) 80048, basic metabolic panel ✓
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- b.) 62311-LT ✓
- c.) 62273-LT
- d.) 62311-LT, 62311-LT, 62311-LT

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- c.) No code is ever necessary as procedure includes all lysis of adhesions
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- a.) No modifier is used because the procedure is already started
- b.) -73
- c.) -74 ✓
- d.) -52

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- a.) 96410
- b.) J0290 ✓
- c.) 36000
- d.) A code from range 99201-05, or 99211-15

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- a.) 15000, 15100 ✓
- b.) 15100
- c.) 14300, 15000
- d.) 13160

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- a.) -77 ✓
- b.) -22
- c.) -51
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- a.) 99291
- b.) The appropriate evaluation and management code
- c.) 99285 ✓
- d.) 99499

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1 /1 pt
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- a.) 67312-LT
- b.) 67311-LT-51
- c.) 67311-LT, 67318-LT ✓

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0 /1 pt
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- a.) 31255-RT, 31256-RT
- b.) 31201-RT, 31020-RT
- c.) 30520-RT, 31255-RT ✓
- d.) 31255-RT

✔ **Correct** 1/1 Points

1 /1 pt
Auto-graded

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- a.) 50945-50 ✓
- b.) 50945-LT-RT
- c.) 50945-LT, 50945-LT, 50945-RT, 50945-RT, 50945-RT

✔ **Correct** 1/1 Points

1 /1 pt
Auto-graded

36. **Which of the following muscular valve controls the flow of digestive juice from the hepatopancreatic duct to the duodenum?**

- (a) Sphincter of Oddi ✓
- (b) Semilunar valve
- (c) Ileocaecal valve
- (d) Pyloric sphincter

✓ Correct 1/1 Points

1 / 1 pt
Auto-graded

37. Which of the following is present on the surface of intestinal epithelial cells?

- (a) Zymogen granules
- (b) Pinocytic vesicles
- (c) Phagocytic vesicles
- (d) Microvilli ✓

✓ Correct 1/1 Points

1 / 1 pt
Auto-graded

38. Lungs are enclosed within

- (a) Perichondrium
- (b) Periosteum
- (c) Pleural membrane ✓
- (d) Pericardium

✓ Correct 1/1 Points

1 / 1 pt
Auto-graded

39. The maximum amount of urea is present in

- (a) Dorsal Aorta
- (b) Hepatic Vein ✓
- (c) Renal Vein
- (d) Hepatic Portal Vein

✓ Correct 1/1 Points

1 / 1 pt
Auto-graded

40. Which of the following organs is known as the "graveyard" of RBCs?

- (a) Spleen ✓
- (b) Kidney
- (c) Liver
- (d) Gall bladder

✓ Correct 1/1 Points

1 / 1 pt
Auto-graded

41. Which of the following organs contains the "Bundle of His"?

- (a) Pancreas
- (b) Brain
- (c) Kidney
- (d) Heart ✓

✓ Correct 1/1 Points

1 /1 pt
Auto-graded

42. Heartbeat originates from the

- (a) papillary muscles
- (b) SA node ✓
- (c) AV node
- (d) Purkinje fibres

✓ Correct 1/1 Points

1 /1 pt
Auto-graded

43. Which of the following features is common in both humans and adult frogs?

- (a) Internal fertilization
- (b) Ureotelic mode of excretion ✓
- (c) Nucleated RBCs
- (d) Four chambered heart

✓ Correct 1/1 Points

1 /1 pt
Auto-graded

44. The basic functional unit of a human kidney is known as

- (a) Nephron ✓
- (b) Pyramid
- (c) Henle's loop nephron
- (d) Nephridia

✓ Correct 1/1 Points

1 /1 pt
Auto-graded

45. Single uriniferous tubule does not contain

- (a) Loop of Henle
- (b) Collecting duct ✓
- (c) Distal convoluted tubule
- (d) Bowman's capsule

✓ Correct 1/1 Points

1 /1 pt
Auto-graded

46. Which of the following joints is immovable?

- (a) Fibrous joint ✓
- (b) Synovial joint
- (c) Cartilaginous joints
- (d) Ball and Socket joint

✓ Correct 1/1 Points

1 /1 pt
Auto-graded

47. The middle portion of the human sperm contains

- (a) Nucleus
- (b) Proteins
- (c) Centriole
- (d) Mitochondria ✓

✓ Correct 1/1 Points

1 /1 pt
Auto-graded

48. Which of the following is the correctly matched pair of an organ and muscles present in the organ?

- (a) Intestine – striated and involuntary
- (b) Upper arm – smooth muscle and fusiform in shape
- (c) Heart – involuntary and unstriated smooth muscle
- (d) Thigh – striated and voluntary ✓

✓ Correct 1/1 Points

1 /1 pt
Auto-graded

49. Cartilage at the end of long bones is

- (a) Calcified cartilage ✓
- (b) Fibrous cartilage
- (c) Hyaline cartilage
- (d) Elastic cartilage

✓ Correct 1/1 Points

1 /1 pt
Auto-graded

50. A deltoid ridge is present in

- (a) Humerus ✓
- (b) Femur
- (c) Radius
- (d) Ulna

Handwritten notes:
A/B
Coordinators
Shubh

Handwritten notes:
Rishant
HOD/BT

Review: Value Added Program Examination - Clinical Trials and Pharmacovigilance (2022-23)

Respondent

30 BOOJITHA.E(BT)

34:31

Time to complete

37/50

Points

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0 / 1 pt
Auto-graded

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- a) Investigated drug
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- c.) 50945-LT, 50945-LT, 50945-RT, 50945-RT, 50945-RT

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1 / 1 pt
Auto-graded

36. Which of the following muscular valve controls the flow of digestive juice from the hepatopancreatic duct to the duodenum?

- (a) Sphincter of Oddi ✓
- (b) Semilunar valve
- (c) Ileocaecal valve
- (d) Pyloric sphincter

✓ Correct 1/1 Points

1 / 1 pt
Auto-graded

37. Which of the following is present on the surface of intestinal epithelial cells?

- (a) Zymogen granules
- (b) Pinocytic vesicles
- (c) Phagocytic vesicles
- (d) Microvilli ✓

✓ Correct 1/1 Points

1 / 1 pt
Auto-graded

38. Lungs are enclosed within

- (a) Perichondrium
- (b) Periosteum
- (c) Pleural membrane ✓
- (d) Pericardium

✓ Correct 1/1 Points

1 / 1 pt
Auto-graded

39. The maximum amount of urea is present in

- (a) Dorsal Aorta
- (b) Hepatic Vein ✓
- (c) Renal Vein
- (d) Hepatic Portal Vein

✓ Correct 1/1 Points

1 / 1 pt
Auto-graded

40. Which of the following organs is known as the "graveyard" of RBCs?

- (a) Spleen ✓
- (b) Kidney
- (c) Liver
- (d) Gall bladder

✓ Correct 1/1 Points

1 / 1 pt
Auto-graded

41. Which of the following organs contains the 'Bundle of His'?

- (a) Pancreas
- (b) Brain
- (c) Kidney
- (d) Heart ✓

✓ Correct 1/1 Points

1 /1 pt
Auto-graded

42. Heartbeat originates from the

- (a) papillary muscles
- (b) SA node ✓
- (c) AV node
- (d) Purkinje fibres

✓ Correct 1/1 Points

1 /1 pt
Auto-graded

43. Which of the following features is common in both humans and adult frogs?

- (a) Internal fertilization
- (b) Ureotelic mode of excretion ✓
- (c) Nucleated RBCs
- (d) Four chambered heart

✓ Correct 1/1 Points

1 /1 pt
Auto-graded

44. The basic functional unit of a human kidney is known as

- (a) Nephron ✓
- (b) Pyramid
- (c) Henle's loop nephron
- (d) Nephridia

✓ Correct 1/1 Points

1 /1 pt
Auto-graded

45. Single uriniferous tubule does not contain

- (a) Loop of Henle
- (b) Collecting duct ✓
- (c) Distal convoluted tubule
- (d) Bowman's capsule

✓ Correct 1/1 Points

1 /1 pt
Auto-graded

46. Which of the following joints is immovable?

- (a) Fibrous joint ✓
- (b) Synovial joint
- (c) Cartilaginous joints
- (d) Ball and Socket joint

✓ Correct 1/1 Points

1 /1 pt
Auto-graded

47. The middle portion of the human sperm contains

- (a) Nucleus
- (b) Proteins
- (c) Centriole
- (d) Mitochondria ✓

✓ Correct 1/1 Points

1 /1 pt
Auto-graded

48. Which of the following is the correctly matched pair of an organ and muscles present in the organ?

- (a) Intestine – striated and involuntary
- (b) Upper arm – smooth muscle and fusiform in shape
- (c) Heart – involuntary and unstriated smooth muscle
- (d) Thigh – striated and voluntary ✓

✗ Incorrect 0/1 Points

0 /1 pt
Auto-graded

49. Cartilage at the end of long bones is

- (a) Calcified cartilage ✓
- (b) Fibrous cartilage
- (c) Hyaline cartilage
- (d) Elastic cartilage

✓ Correct 1/1 Points

1 /1 pt
Auto-graded

50. A deltoid ridge is present in

- (a) Humerus ✓
- (b) Femur
- (c) Radius
- (d) Ulna

Handwritten signature
Coordinator

Handwritten signature
HOD / B5

Review: Value Added Program Examination - Clinical Trials and Pharmacovigilance (2022-23)

Respondent

31 SUDHARSON.M(BT)

32:14
Time to complete

44/50
Points

✓ Correct 1/1 Points

1 / 1 pt
Auto-graded

1. Which of the following are not correct on the basis of clinical trials?

- a) Biomedical research studies
- b) Behavioral research studies
- c) Studies on human subjects
- d) Study based only on animals ✓

✓ Correct 1/1 Points

1 / 1 pt
Auto-graded

2. What is the full form of IND?

- a) Investigated drug
- b) Investigation Application
- c) Investigation of New Drug Application ✓
- d) Under Investigation

✓ Correct 1/1 Points

1 / 1 pt
Auto-graded

3. What is meant by a blind subject?

- a) The subjects do not know which study treatment they receive ✓
- b) Patients injected with placebo and active doses
- c) Fake treatment
- d) Signed document of the recruited patient for the clinical trial procedures

✓ Correct 1/1 Points

1 / 1 pt
Auto-graded

4. What is placebo?

- a) The subjects do not know which study treatment they receive
- b) Patients injected with placebo and active doses
- c) Fake treatment ✓
- d) Signed document of the recruited patient for the clinical trial procedures

✓ **Correct** 1/1 Points

1 /1 pt
Auto-graded

5. **What is informed consent in a clinical trial?**

- a) The subjects do not know which study treatment they receive
- b) Patients injected with placebo and active doses
- c) Fake treatment
- d) Signed document of the recruited patient for the clinical trial procedures ✓

✓ **Correct** 1/1 Points

1 /1 pt
Auto-graded

6. **Which one of the following is the last step of a clinical trial process?**

- a) Investigator selection
- b) Patient recruitment
- c) Statistical Analysis
- d) Data filed and registration ✓

✓ **Correct** 1/1 Points

1 /1 pt
Auto-graded

7. **How many people will be selected for phase I trial?**

- a) The whole market will be under surveillance
- b) 300-3000 people
- c) 20-300 people
- d) 20-50 people ✓

✓ **Correct** 1/1 Points

1 /1 pt
Auto-graded

8. **Which of the following country is the most attractive location to perform clinical trials outside the United States?**

- a) India
- b) China ✓
- c) United Kingdom
- d) Germany

✗ **Incorrect** 0/1 Points

0 /1 pt
Auto-graded

9. **In which phase pharmacodynamics and pharmacokinetics of a drug are studied?**

- a) Phase I ✓
- b) Phase II
- c) Phase III
- d) Phase IV

✓ Correct 1/1 Points

1 / 1 pt
Auto-graded

10. What is the full form of SAD?

- a) Secure Assessing dose
- b) Single Ascending Dose ✓
- c) Sodium Ascending Dose
- d) Single Amount Dose

✓ Correct 1/1 Points

1 / 1 pt
Auto-graded

11. What is the full form of MAD?

- a) Multiple Ascending Dose ✓
- b) Managing Abnormalities Dose
- c) Managing absorption dose
- d) Managing Assimilation Dose

✗ Incorrect 0/1 Points

0 / 1 pt
Auto-graded

12. Which of the trial phase is for pharmacovigilance?

- a) Phase I
- b) Phase II
- c) Phase III
- d) Phase IV ✓

✓ Correct 1/1 Points

1 / 1 pt
Auto-graded

13. What is GCP?

- a) Good cooperation project
- b) Good clinical practice ✓
- c) Good cleanliness practice
- d) Good Constructor provider

✓ Correct 1/1 Points

1 / 1 pt
Auto-graded

14. GCP include protection of Human rights as a subject in a clinical trial.

- a) True ✓
- b) False

✓ Correct 1/1 Points

1 / 1 pt
Auto-graded

15. What does the symbol Rx mean?

- a) To take ✓
- b) Should date
- c) How to take
- d) What to take

✓ Correct 1/1 Points

1 / 1 pt
Auto-graded

16. What does the abbreviation o.d? means on a prescription?

- a) Name of medicine
- b) How to take the medicine
- c) Quantity to be dispensed
- d) Once daily ✓

✓ Correct 1/1 Points

1 / 1 pt
Auto-graded

17. How many diagnosis and CPT codes are reported on the ambulatory care records on the examinations?

- a) 4 diagnosis, as many CPT procedures as necessary
- b) 4 diagnosis, 4 CPT procedure codes ✓
- c) As many codes as necessary in both categories

✓ Correct 1/1 Points

1 / 1 pt
Auto-graded

18. A patient undergoes a colonoscopy for possible polyp removal. By hot biopsy forceps, a polyp is removed from the descending colon, and by snare technique, a polyp is removed further up just into the transverse colon. What CPT code(s) are reported by the FACILITY?

- a.) 45385, 45384-59 ✓
- b.) 45384, 45385-51
- c.) 45385
- d.) 45384

✗ Incorrect 0/1 Points

0 / 1 pt
Auto-graded

19. For question #2 what code (s) would be reported for the SURGEON?

- a.) 45385, 45384-59 ✓
- b.) 45385, 45384-51
- c.) 45385
- d.) 45384

✓ Correct 1/1 Points

1 /1 pt
Auto-graded

20. **Double osteotomy bunionectomy to correct severe hallux valgus of the left first metatarsal with 0.062 K wire fixation and application of cast.**

- a.) 28296-TA
- b.) 28299-TA ✓
- c.) 28296-TA, 29425-TA
- d.) 28299-LT

✓ Correct 1/1 Points

1 /1 pt
Auto-graded

21. **Esophagogastroduodenoscopy with dilation of the esophagus over a guide wire at same operative episode.**

- a.) 43453, 43235-59
- b.) 43226, 43235-59
- c.) 43248 ✓
- d.) 43456, 43235

✓ Correct 1/1 Points

1 /1 pt
Auto-graded

22. **Excision of 6-cm inclusion cyst of left neck located below the fascia, entire dissection of tumor from the subfascia; closure of deep fascia with 3-0 Vicryl; skin closed with 4-0 Maxon. Steri-strips were applied.**

- a.) 21556 ✓
- b.) 11426, 12042-59
- c.) 11426
- d.) 21557

✓ Correct 1/1 Points

1 /1 pt
Auto-graded

23. **A patient with thoracic vertebral fractures of the spine presents for a percutaneous vertebroplasty. A needle is inserted through the right pedicle of the T7 and T8 vertebral body defects and methyl methacrylate is injected. The procedure was done under fluoroscopic guidance. What codes are reported for the facility?**

- a.) 22305, 76013-TC
- b.) 22325, 76012-TC
- c.) 22305, 76012-TC
- d.) 22520, 22522, 76012-TC ✓

✓ Correct 1/1 Points

1 / 1 pt
Auto-graded

24. **Supervision and interpretation (professional component) for one view study of the ankle provided by the physician.**

- a.) 73600-52-26 ✓
- b.) 73600
- c.) 76499-26

✓ Correct 1/1 Points

1 / 1 pt
Auto-graded

25. **Laboratory components of calcium (82310), carbon dioxide (82374), chloride (82435), creatinine (82565), glucose (82947), potassium (84132), sodium (84295), and nitrogen-BUN (84520) compose what panel?**

- a.) No panel, code all as individual codes
- b.) 80048, basic metabolic panel ✓
- c.) 80050, general health panel
- d.) 80051, electrolyte panel

✓ Correct 1/1 Points

1 / 1 pt
Auto-graded

26. **A patient complains of severe lower back and leg pain, which are not responding to conservative treatment. A lumbar caudal injection is given with three injections at the left L4-L5 level for pain relief.**

- a.) 62289-LT
- b.) 62311-LT ✓
- c.) 62273-LT
- d.) 62311-LT, 62311-LT, 62311-LT

✓ Correct 1/1 Points

1 / 1 pt
Auto-graded

27. **The following is true in relation to the CPT coding of lysis of adhesions:**

- a.) Always code lysis of adhesions when mentioned.
- b.) An additional code is assigned only when the adhesions are extensive and required additional resources to complete the surgery ✓
- c.) No code is ever necessary as procedure includes all lysis of adhesions
- d.) Assign the code for lysis of adhesion with modifier -59

✓ Correct 1/1 Points

1 /1 pt
Auto-graded

28. Which HCPCS modifier is used to indicate cancellation of surgery after anesthesia due to poor patient condition?

- a.) No modifier is used because the procedure is already started
- b.) -73
- c.) -74 ✓
- d.) -52

✓ Correct 1/1 Points

1 /1 pt
Auto-graded

29. Which national code is used to report administration of Ampicillin sodium, 500 mg IV?

- a.) 96410
- b.) J0290 ✓
- c.) 36000
- d.) A code from range 99201-05, or 99211-15

✓ Correct 1/1 Points

1 /1 pt
Auto-graded

30. Patient receives a 60 sq cm split thickness skin graft for extensive partial skin thickness wounds on the arm with excisional preparation of the site performed.

- a.) 15000, 15100 ✓
- b.) 15100
- c.) 14300, 15000
- d.) 13160

✓ Correct 1/1 Points

1 /1 pt
Auto-graded

31. Surgeon A performs a surgical procedure early in the morning. Later that day, the patient experiences complications, and Surgeon B repeats the entire procedure. What level I modifier would Surgeon B append to the surgical CPT code?

- a.) -77 ✓
- b.) -22
- c.) -51
- d.) -59

✘ Incorrect 0/1 Points

0 / 1 pt
Auto-graded

32. **Critical care given for less than 30 minutes total duration on a given date should be reported as:**

- a.) 99291
- b.) The appropriate evaluation and management code
- c.) 99285 ✓
- d.) 99499

✓ Correct 1/1 Points

1 / 1 pt
Auto-graded

33. **Strabismus surgery. Recession of medial rectus muscle of left eye; strabismus surgery on superior oblique muscle of right eye.**

- a.) 67312-LT
- b.) 67311-LT-51
- c.) 67311-LT, 67318-LT ✓

✓ Correct 1/1 Points

1 / 1 pt
Auto-graded

34. **The patient undergoes a right endoscopic total ethmoidectomy, septoplasty with submucous resection.**

- a.) 31255-RT, 31256-RT
- b.) 31201-RT, 31020-RT
- c.) 30520-RT, 31255-RT ✓
- d.) 31255-RT

✓ Correct 1/1 Points

1 / 1 pt
Auto-graded

35. **A patient has several calculi of the right and left ureter. A laparoscopic surgical ureterolithotomy is performed and 2 calculi are taken from the left side, 3 from the right.**

- a.) 50945-50 ✓
- b.) 50945-LT-RT
- c.) 50945-LT, 50945-LT, 50945-RT, 50945-RT, 50945-RT

✓ Correct 1/1 Points

1 / 1 pt
Auto-graded

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✓ Correct 1/1 Points

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- (b) Pyramid
- (c) Henle's loop nephron
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✗ Incorrect 0/1 Points

0 / 1 pt
Auto-graded

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1 / 1 pt
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0 / 1 pt
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- (b) Fibrous cartilage
- (c) Hyaline cartilage
- (d) Elastic cartilage

✓ Correct 1/1 Points

1 / 1 pt
Auto-graded

50. A deltoid ridge is present in

- (a) Humerus ✓
- (b) Femur
- (c) Radius
- (d) Ulna

Handwritten notes:
A diagram of a humerus with an arrow pointing to the deltoid ridge. The word "Coordinators" is written below the diagram. To the right, there is a signature and the name "P. J. M. H. H. O. A. / B. T."

Handwritten notes:
P. J. M. H. H. O. A. / B. T.



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S.P.G.Chidambara Nadar - C.Nagammal Campus
S.P.G.C. Nagar, K.Vellakulam - 625 701 (Near VIRUDHUNAGAR).

Department of Biotechnology

Value Added Course on "Clinical Research and Pharmacovigilance"

Roll Number	Register Number	Student Name	Marks (100)
20UBT001	920420UBT001	SRIDIVYA.R	93
20UBT002	920420UBT002	SUDHARSAN.M	92
20UBT003	920420UBT003	JEFFRY DANIEL.D	87
20UBT004	920420UBT004	GIRITHARAN.S	92
20UBT005	920420UBT005	SIVA SANKAR.K	87
20UBT006	920420UBT006	THILSATH MEERAL.S	92
20UBT007	920420UBT007	GOBIKA.G	AB
20UBT008	920420UBT008	FAHEEMA THAHASEEN.A	93
20UBT009	920420UBT009	SANDOSHMANI.R	93
20UBT010	920420UBT010	RAVINA.R	92
20UBT011	920420UBT011	MOULI MONISHA.V	88
20UBT012	920420UBT012	ARAVIND.R	86
20UBT013	920420UBT013	AKASH DEV.M.S	81
20UBT014	920420UBT014	KEERTHI VASAN.V	94
20UBT015	920420UBT015	DINESH.R	89
20UBT016	920420UBT016	BENITA MARGARET.L	79
20UBT017	920420UBT017	JASMINE KILDA.L	92
20UBT018	920420UBT018	MADHUMITHA.K	93
20UBT019	920420UBT019	DEEJITH NAATIYAAL.M.S	85
20UBT020	920420UBT020	KAMALI.S	95
20UBT021	920420UBT021	SINDHUJA.S	87
20UBT022	920420UBT022	NITHYASREE.A	79
20UBT023	920420UBT023	VARSHINIRAJI.P	86
20UBT024	920420UBT024	ABINAYA.J	93
20UBT025	920420UBT025	SAIBHAVADHARANI.B	94
20UBT026	920420UBT026	GOKULNATH.S	87
20UBT027	920420UBT027	SUBHIKSHA.S	93
20UBT028	920420UBT028	VARSHA.G.V	86
20UBT029	920420UBT029	RINISHA.R	92
20UBT030	920420UBT030	NARASINGAM.R	91
20UBT031	920420UBT031	JOHN PAUL HUDSON.S	91
20UBT032	920420UBT032	JEGADEESH.M	93
20UBT033	920420UBT033	VAIRAMUTHU.P	92
20UBT034	920420UBT034	VAISHAALI.A.M	94
20UBT035	920420UBT035	YOGASRI.M	93
20UBT036	920420UBT036	BOOJITHA.E	85



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20UBT037	920420UBT037	LAMIYA BANU.M	91
20UBT038	920420UBT038	VARSHA.E	70
20UBT039	920420UBT039	SAKTHI SUREGA.P	93
20UBT040	920420UBT040	GOWSALYA.K	90
20UBT041	920420UBT041	MINUSHA.S	AB
20UBT042	920420UBT042	VINODHINI.R	90
20UBT043	920420UBT043	CERLICLADIYA.P	93
20UBT044	920420UBT044	SHANKAR GANESH.M.V	86
20UBT045	920420UBT045	HARSINI.S	93
20UBT046	920420UBT046	PRASANNA VENGATESH.V	91
20UBT047	920420UBT047	AASIF HUSSAIN	AB
20UBT049	920120UBT049	NITHYASHREE.S.R	92

No. of Hours: 32

Credits Recommended: 2


Coordinators


HOD/BT


R.J. - Sar
3/1/17 ms

Roll Number	Register Number	Student Name	Continuous Assessment (100)	Final (100)	Continuous Assessment (60)	Final (40)	Total (100)
20UBT001	920420UBT001	SRIDIVYA.R	92	94	55.2	37.6	93
20UBT002	920420UBT002	SUDHARSAN.M	95	88	57	35.2	92
20UBT003	920420UBT003	JEFFRY DANIEL.D	85	90	51	36	87
20UBT004	920420UBT004	GIRITHARAN.S	87	100	52.2	40	92
20UBT005	920420UBT005	SIVA SANKARI.K	89	84	53.4	33.6	87
20UBT006	920420UBT006	THILSATH MEERAL.S	90	94	54	37.6	92
20UBT007	920420UBT007	GOBIKA.G	AB	AB	AB	AB	AB
20UBT008	920420UBT008	FAHEEMA THAHASEEN.A	93	94	55.8	37.6	93
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20UBT017	920420UBT017	JASMINE KILDA.L	90	94	54	37.6	92
20UBT018	920420UBT018	MADHUMITHA.K	91	96	54.6	38.4	93
20UBT019	920420UBT019	DEEJITH NAATIYAAL.M.S	88	80	52.8	32	85
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Department of Biotechnology

Value Added Course on "Clinical Research and Pharmacovigilance"

Roll Number	Register Number	Student Name	Continuous Assessment (100)	Final (100)	Continuous Assessment (60)	Final (40)	Total (100)
20UBT033	920420UBT033	VAIRAMUTHU.P	87	100	52.2	40	92
20UBT034	920420UBT034	VAISHAALI.A.M	94	94	56.4	37.6	94
20UBT035	920420UBT035	YOGASRI.M	92	94	55.2	37.6	93
20UBT036	920420UBT036	BOOJITHA.E	93	74	55.8	29.6	85
20UBT037	920420UBT037	LAMIYA BANU.M	90	92	54	36.8	91
20UBT038	920420UBT038	VARSHA.E	90	40	54	16	70
20UBT039	920420UBT039	SAKTHI SUREGA.P	93	94	55.8	37.6	93
20UBT040	920420UBT040	GOWSALYA.K	88	92	52.8	36.8	90
20UBT041	920420UBT041	MINUSHA.S	30	AB	18	AB	AB
20UBT042	920420UBT042	VINODHINI.R	92	88	55.2	35.2	90
20UBT043	920420UBT043	CERLICLADIYA.P	93	94	55.8	37.6	93
20UBT044	920420UBT044	SHANKAR GANESH.M.V	92	78	55.2	31.2	86
20UBT045	920420UBT045	HARSINI.S	92	94	55.2	37.6	93
20UBT046	920420UBT046	PRASANNA VENGATESH.V	92	90	55.2	36	91
20UBT047	920420UBT047	AASIF HUSSAIN	AB	86	AB	34.4	AB
20UBT049	920120UBT049	NITHYASHREE.S.R	90	96	54	38.4	92


Coordinators


HOD/BT



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S.P.G.Chidambara Nadar - C.Nagammal Campus

S.P.G.C. Nagar, K.Vellakulam - 625 701 (Near VIRUDHUNAGAR).

Department of Biotechnology

Value Added Course on "Clinical Research and Pharmacovigilance"

Internal Assessment Marks

Roll Number	Register Number	Student Name	IAT 1 (10)	IAT 2 (30)	IAT 3 (60)	TOTAL (100)
20UBT001	920420UBT001	SRIDIVYA.R	10	27	55	92
20UBT002	920420UBT002	SUDHARSAN.M	10	30	55	95
20UBT003	920420UBT003	JEFFRY DANIEL.D	10	25	50	85
20UBT004	920420UBT004	GIRITHARAN.S	10	27	50	87
20UBT005	920420UBT005	SIVA SANKARI.K	10	29	50	89
20UBT006	920420UBT006	THILSATH MEERAL.S	10	30	50	90
20UBT007	920420UBT007	GOBIKA.G	AB	AB	AB	AB
20UBT008	920420UBT008	FAHEEMA THAHASEEN.A	10	28	55	93
20UBT009	920420UBT009	SANDOSHMANI.R	10	28	55	93
20UBT010	920420UBT010	RAVINA.R	10	28	55	93
20UBT011	920420UBT011	MOULI MONISHA.V	10	27	50	87
20UBT012	920420UBT012	ARAVIND.R	10	27	50	87
20UBT013	920420UBT013	AKASH DEV.M.S	10	26	55	91
20UBT014	920420UBT014	KEERTHI VASAN.V	10	30	50	90
20UBT015	920420UBT015	DINESH.R	10	28	50	88
20UBT016	920420UBT016	BENITA MARGARET.L	10	28	55	93
20UBT017	920420UBT017	JASMINE KILDA.L	10	30	50	90
20UBT018	920420UBT018	MADHUMITHA.K	10	26	55	91
20UBT019	920420UBT019	DEEJITH NAATIYAAL.M.S	10	28	50	88
20UBT020	920420UBT020	KAMALI.S	10	30	55	95
20UBT021	920420UBT021	SINDHUJA.S	10	27	50	87
20UBT022	920420UBT022	NITHYASREE.A	10	26	55	91
20UBT023	920420UBT023	VARSHINIRAJI.P	10	27	55	92
20UBT024	920420UBT024	ABINAYA.J	10	29	55	94
20UBT025	920420UBT025	SAIBHAVADHARANI.B	10	26	55	91
20UBT026	920420UBT026	GOKULNATH.S	10	26	50	86
20UBT027	920420UBT027	SUBHIKSHA.S	10	26	55	91
20UBT028	920420UBT028	VARSHA.G.V	10	28	50	88
20UBT029	920420UBT029	RINISHA.R	10	30	55	95
20UBT030	920420UBT030	NARASINGAM.R	10	27	50	87
20UBT031	920420UBT031	JOHN PAUL HUDSON.S	10	30	50	90
20UBT032	920420UBT032	JEGADEESH.M	10	28	55	93
20UBT033	920420UBT033	VAIRAMUTHU.P	10	27	50	87
20UBT034	920420UBT034	VAISHAALI.A.M	10	29	55	94
20UBT035	920420UBT035	YOGASRI.M	10	27	55	92
20UBT036	920420UBT036	BOOJITHA.E	10	28	55	93
20UBT037	920420UBT037	LAMIYA BANU.M	10	30	50	90
20UBT038	920420UBT038	VARSHA.E	10	30	50	90
20UBT039	920420UBT039	SAKTHI SUREGA.P	10	28	55	93



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Department of Biotechnology

Value Added Course on "Clinical Research and Pharmacovigilance"

Internal Assessment Marks

Roll Number	Register Number	Student Name	IAT 1 (10)	IAT 2 (30)	IAT 3 (60)	TOTAL (100)
20UBT040	920420UBT040	GOWSALYA.K	10	28	50	88
20UBT041	920420UBT041	MINUSHA.S	AB	30	AB	30
20UBT042	920420UBT042	VINODHINI.R	10	27	55	92
20UBT043	920420UBT043	CERLICLADIYA.P	10	28	55	93
20UBT044	920420UBT044	SHANKAR GANESH.M.V	10	27	55	92
20UBT045	920420UBT045	HARSINI.S	10	27	55	92
20UBT046	920420UBT046	PRASANNA VENGATESH.V	10	27	55	92
20UBT047	920420UBT047	AASIF HUSSAIN	AB	AB	AB	AB
20UBT049	920120UBT049	NITHYASHREE.S.R	10	25	55	90




Coordinators


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Department of Biotechnology

Value Added Course on "Clinical Research and Pharmacovigilance"

Final Exam Marks

Roll Number	Register Number	Student Name	Marks (50)	Marks (100)
20UBT001	920420UBT001	SRIDIVYA.R	47	94
20UBT002	920420UBT002	SUDHARSAN.M	44	88
20UBT003	920420UBT003	JEFFRY DANIEL.D	45	90
20UBT004	920420UBT004	GIRITHARAN.S	50	100
20UBT005	920420UBT005	SIVA SANKARI.K	42	84
20UBT006	920420UBT006	THILSATH MEERAL.S	47	94
20UBT007	920420UBT007	GOBIKA.G	AB	AB
20UBT008	920420UBT008	FAHEEMA THAHASEEN.A	47	94
20UBT009	920420UBT009	SANDOSHMANI.R	47	94
20UBT010	920420UBT010	RAVINA.R	45	90
20UBT011	920420UBT011	MOULI MONISHA.V	45	90
20UBT012	920420UBT012	ARAVIND.R	42	84
20UBT013	920420UBT013	AKASH DEV.M.S	33	66
20UBT014	920420UBT014	KEERTHI VASAN.V	50	100
20UBT015	920420UBT015	DINESH.R	45	90
20UBT016	920420UBT016	BENITA MARGARET.L	29	58
20UBT017	920420UBT017	JASMINE KILDA.L	47	94
20UBT018	920420UBT018	MADHUMITHA.K	48	96
20UBT019	920420UBT019	DEEJITH NAATIYAAL.M.S	40	80
20UBT020	920420UBT020	KAMALI.S	47	94
20UBT021	920420UBT021	SINDHUJA.S	44	88
20UBT022	920420UBT022	NITHYASREE.A	31	62
20UBT023	920420UBT023	VARSHINIRAJI.P	38	76
20UBT024	920420UBT024	ABINAYA.J	46	92
20UBT025	920420UBT025	SAIBHAVADHARANI.B	49	98
20UBT026	920420UBT026	GOKULNATH.S	44	88
20UBT027	920420UBT027	SUBHIKSHA.S	48	96
20UBT028	920420UBT028	VARSHA.G.V	42	84
20UBT029	920420UBT029	RINISHA.R	44	88
20UBT030	920420UBT030	NARASINGAM.R	49	98
20UBT031	920420UBT031	JOHN PAUL HUDSON.S	46	92
20UBT032	920420UBT032	JEGADEESH.M	47	94
20UBT033	920420UBT033	VAIRAMUTHU.P	50	100
20UBT034	920420UBT034	VAISHAALI.A.M	47	94
20UBT035	920420UBT035	YOGASRI.M	47	94
20UBT036	920420UBT036	BOOJITHA.E	37	74



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Department of Biotechnology


Value Added Course on "Clinical Research and Pharmacovigilance"

Final Exam Marks

Roll Number	Register Number	Student Name	Marks (50)	Marks (100)
20UBT037	920420UBT037	LAMIYA BANU.M	46	92
20UBT038	920420UBT038	VARSHA.E	20	40
20UBT039	920420UBT039	SAKTHI SUREGA.P	47	94
20UBT040	920420UBT040	GOWSALYA.K	46	92
20UBT041	920420UBT041	MINUSHA.S	AB	AB
20UBT042	920420UBT042	VINODHINI.R	44	88
20UBT043	920420UBT043	CERLICLADIYA.P	47	94
20UBT044	920420UBT044	SHANKAR GANESH.M.V	39	78
20UBT045	920420UBT045	HARSINI.S	47	94
20UBT046	920420UBT046	PRASANNA VENGATESH.V	45	90
20UBT047	920420UBT047	AASIF HUSSAIN	43	86
20UBT049	920120UBT049	NITHYASHREE.S.R	48	96



Coordinators


HOD / BT

Review: FEED BACK ON Value-Added Course on "Clinical Research and Pharmacovigilance"

Respondent

23

NITHYASREE.A(BT)

00:45

Time to complete

1. NAME

Score / 0 pts

Nithyasree. A

2. DEPARTMENT

Score / 0 pts

Biotechnology

3. YEAR

Score / 0 pts

3

4. Where the objective of the event met

Score / 0 pts

- Completely agree
- Strongly agree
- Agree
- Partially agree
- Disagree

5. Was the programme sequence well planned

Score / 0 pts

- Completely agree
- Strongly agree
- Agree
- Partially agree
- Disagree

6. Were the lecturer clear and easy to understand

Score / 0 pts

- Completely agree
- Strongly agree
- Agree
- Partially agree
- Disagree

7. Whether the instructor encouraged the interaction

Score / 0 pts

- Completely agree
- Strongly agree
- Agree
- Partially agree
- Disagree

8. The information presented at this event was highly beneficial

Score / 0 pts

- Completely agree
- Strongly agree
- Agree
- Partially agree
- Disagree

9. Organisation of the event was good

Score / 0 pts

- Completely agree
- Strongly agree
- Agree
- Partially agree
- Disagree

10. Comments/Suggestions

Score / 0 pts

No answer provided.


Coordinators

P. I. H. M. A. S.
HOD / BT

Review: FEED BACK ON Value-Added Course on "Clinical Research and Pharmacovigilance"

Respondent

10 LAMIYA BANU.M(BT)

01:16

Time to complete

1. NAME

Score / 0 pts

M.lamiya Banu

2. DEPARTMENT

Score / 0 pts

Biotechnology

3. YEAR

Score / 0 pts

3rd

4. Where the objective of the event met

Score / 0 pts

- Completely agree
- Strongly agree
- Agree
- Partially agree
- Disagree

5. Was the programme sequence well planned

Score / 0 pts

- Completely agree
- Strongly agree
- Agree
- Partially agree
- Disagree

6. Were the lecturer clear and easy to understand

Score / 0 pts

- Completely agree
- Strongly agree
- Agree
- Partially agree
- Disagree

7. Whether the instructor encouraged the interaction

Score / 0 pts

- Completely agree
- Strongly agree
- Agree
- Partially agree
- Disagree

8. The information presented at this event was highly beneficial

Score / 0 pts

- Completely agree
- Strongly agree
- Agree
- Partially agree
- Disagree

9. Organisation of the event was good

Score / 0 pts

- Completely agree
- Strongly agree
- Agree
- Partially agree
- Disagree

10. Comments/Suggestions

Score / 0 pts

No answer provided.

Handwritten notes:
P.1/16
Coordinators
Structure

Handwritten signature:
P.1/16
HoA/BT

Review: FEED BACK ON Value-Added Course on "Clinical Research and Pharmacovigilance"

Respondent

45 BOOJITHA.E(BT)

00:40

Time to complete

1. NAME

Score / 0 pts

E.Boojitha

2. DEPARTMENT

Score / 0 pts

Biotechnology

3. YEAR

Score / 0 pts

3

4. Where the objective of the event met

Score / 0 pts

- Completely agree
- Strongly agree
- Agree
- Partially agree
- Disagree

5. Was the programme sequence well planned

Score / 0 pts

- Completely agree
- Strongly agree
- Agree
- Partially agree
- Disagree

6. Were the lecturer clear and easy to understand

Score: / 0 pts

- Completely agree
- Strongly agree
- Agree
- Partially agree
- Disagree

7. Whether the instructor encouraged the interaction

Score: / 0 pts

- Completely agree
- Strongly agree
- Agree
- Partially agree
- Disagree

8. The information presented at this event was highly beneficial

Score: / 0 pts

- Completely agree
- Strongly agree
- Agree
- Partially agree
- Disagree

9. Organisation of the event was good

Score: / 0 pts

- Completely agree
- Strongly agree
- Agree
- Partially agree
- Disagree

10. Comments/Suggestions

Score: / 0 pts

No answer provided.

[Handwritten signature]
[Handwritten signature]
[Handwritten signature]
Coordinators

[Handwritten signature]
HOD (B)

FEED BACK ON Value-Added Course on "Clinical Research and Pharmacovigilance"

46
Responses

01:02
Average time to complete

Active
Status

1. NAME (0 point)

46
Responses

Latest Responses

"Gokulnath.S"

"E.Boojitha"

"Aasif Hussain"

2. DEPARTMENT (0 point)

46
Responses

Latest Responses

"Biotechnology"

"Biotechnology "

"Biotechnology "

3. YEAR (0 point)


46
Responses

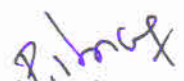
Latest Responses

"3"

"3"

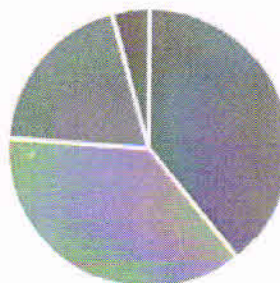
"3rd"


Coordinators


HOD/BS

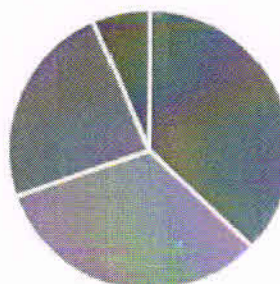
4. Where the objective of the event met (0 point)

● Completely agree	18
● Strongly agree	17
● Agree	9
● Partially agree	2
● Disagree	0



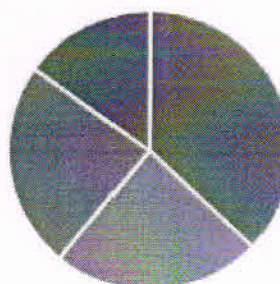
5. Was the programme sequence well planned (0 point)

● Completely agree	17
● Strongly agree	15
● Agree	11
● Partially agree	3
● Disagree	0



6. Were the lecturer clear and easy to understand (0 point)

● Completely agree	17
● Strongly agree	11
● Agree	11
● Partially agree	7
● Disagree	0

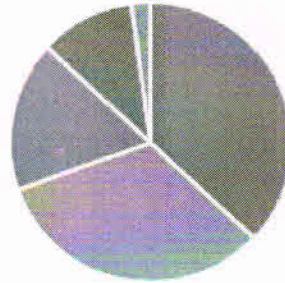


[Handwritten signature]
Coordinators

[Handwritten signature]
HOD/BT

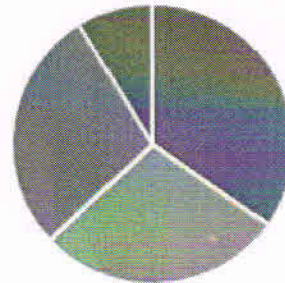
7. Whether the instructor encouraged the interaction (0 point)

● Completely agree	17
● Strongly agree	15
● Agree	8
● Partially agree	5
● Disagree	1



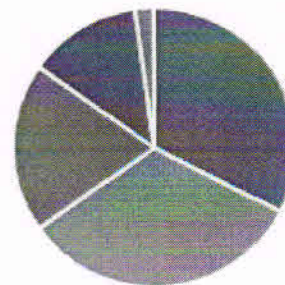
8. The information presented at this event was highly beneficial (0 point)

● Completely agree	16
● Strongly agree	13
● Agree	13
● Partially agree	4
● Disagree	0



9. Organisation of the event was good (0 point)

● Completely agree	15
● Strongly agree	15
● Agree	9
● Partially agree	6
● Disagree	1



10. Comments/Suggestions (0 point)

9

Responses

Handwritten signatures and text:
F. J. B. / H. B. / L. B. /
Coordinators

Latest Responses

"No"

Handwritten text:
L. B. / H. B. /
1-60/B1



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DEPARTMENT OF BIOTECHNOLOGY

Industry Certified Value-Added Course

On

CLINICAL RESEARCH AND PHARMACOVIGILANCE

In association with

Deepam Hospital, Chennai.

06-02-2023 to 09-02-2023

SUMMARY REPORT

A four days industry-certified value-added course entitled “**Clinical Research and Pharmacovigilance**” was organised by the Department of Biotechnology, Kamaraj College of Engineering and Technology, Virudhunagar, in association with Deepam Hospitals, Chennai, for **III Year B. Tech Biotechnology** students from **06-02-2023 to 09-02-2023**. Two trainers, Mr Rajavelu and Mr Dhayalan from Deepam Academy of Medical Sciences, handled the sessions. The primary objective of this program is to provide an understanding of clinical research and its scope in drug discovery process and to provide Hands-on training on tools related to Clinical Data Management and Pharmacovigilance. In addition, this course helped the students develop the skills required to work in Clinical Research, Clinical Data Management and Pharmacovigilance.

Day 1 started with a short **inaugural function** where our Head of the Department welcomed and felicitated the gathering. Then, one of the program coordinators, Dr A. Ronaldo Anuf, introduced the theme of the Value added course. Next, the external trainers handled a session on an overview of the basics of clinical research and clinical pharmacology. Then, in the afternoon, they provided an overview of the Drug Development Process, Clinical trial design and trial document preparation. Finally, the trainers also gave an introductory session on the requirements for SAS[®] programming and hands-on training on the basics of Python Programming.

Day 2 started with a session on Ethics, Guidelines & Regulations, and Roles and Responsibilities of Clinical Research Professionals, followed by a session on an Overview of CDM, 21CFR part 11-EDC, CDISC Regulations, GCDMP, and Protocol review and CRF design. In the afternoon, the trainers gave a hands-on session on database setup, design, and validation; data entry and validation; Coding and dictionaries; Database lock and form filing.

Day 3 started with a lecture on Good Clinical Practice (GCP), followed by hands-on training sessions on SAS® Programming. A short assessment was also conducted at the end of the third day.

Day 4 and the final day of the program started with a lecture on the aims and roles of Pharmacovigilance, followed by the training session on Key Performance Indicators, Databases, Naranjo algorithms and PV Prediction. Another short assessment was also conducted on the day. Finally, the day was concluded with the Valedictory session. Dr S. Senthil, Principal of Kamaraj College of Engineering and Technology, attended the valedictory session and handed the certificates to the students. Overall the students learnt the practical aspects of important Pharmacovigilance activities per the global standards and acquired the necessary skills and knowledge to work in Clinical Research Organizations.



Program Coordinator(s)



HOD / BT



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S.P.G.C. Nagar, K.Vellakulam - 625 701 (Near VIRUDHUNAGAR)

DEPARTMENT OF BIOTECHNOLOGY

Industry Certified Value-Added Course

On

CLINICAL RESEARCH AND PHARMACOVIGILANCE

In association with

Deepam Hospital, Chennai.

06-02-2023 to 09-02-2023

EXPENDITURE DETAILS

Program Coordinators: Dr R. Baskaran, Dr A. Ronaldo Anuf, Er Karl Joseph Samuel				
S. No	Particulars	Bill No	Date	Amount (₹)
1.	Deepam Hospital – Training Fee for 48 Students (48 × 1000)	Invoice No. 1	06-02-2023	48,000.00
2.	KCET Canteen - Breakfast, Lunch for 2 Trainers (4 Days)		06-02-2023 to 09-02-2023	
3.	KCET Canteen - Tea & Snacks for 2 Trainers (4 Days)		06-02-2023 to 09-02-2023	
4.	KCET Boys Hostel Mess - Dinner for 2 Trainers (4 Days)		06-02-2023 to 09-02-2023	
5.	KCET Boys Hostel - Accommodation for 2 Trainers (4 Days)		06-02-2023 to 09-02-2023	
TOTAL				

ABSTRACT

Amount to be settled by office via Online Account Transfer (S. No 1)

Rs. 48,000 /-

Account Details	Amount to be transferred
Deepam Hospitals (S. No: 1) Name of the account Holder : Deepam Hospitals and Wellness Enterprises Name of the Bank : ICICI Bank Name of the Branch : Urakkam Account No : 321805001145 IFSC Code : ICIC0003218 PAN No : BFRPK6352J	Rs. 48,000 /-

Program Coordinator(s)

HOD / BT

Deepam Hospital

17/22, M.K.Reddy Street,
West Tambaram,
Chennai 600045

Phone no. : 7305979772

Email : info@deepamhospitals.com

GSTIN : 33AABCD1285G1Z0

State: 33-Tamil Nadu



Tax Invoice

Bill To

Kamaraj College Of Engineering &Tech

Invoice No. : 1

Date : 14-02-2023

#	Item name	HSN/ SAC	Quantity	Price/ Unit	Amount
1	Clinical Research,CDM& Pharmacovigilance		48	₹ 1,000.00	₹ 48,000.00
Total			48		₹ 48,000.00

Invoice Amount In Words

Forty Eight Thousand Rupees only

Terms and Conditions

Thanks for doing business with us!

Sub Total ₹ 48,000.00

Total ₹ 48,000.00

Received ₹ 0.00

Balance ₹ 48,000.00

For : Deepam Hospital

Authorized Signatory

