

REPORT

	<p>SHORT TERM CERTIFICATE COURSE Under (GTU-CCE)</p>	
<p>GTU – Centre for Continuing Education On</p> <p>“Clinical Research and Pharmacovigilance”</p> <p>ORGANISED BY</p> <p>ROFEL SHRI G. M. BILAKHIA COLLEGE OF PHARMACY, VAPI.</p>		

(19 March 2023 to 04 June 2023)



Short Term Certificate Course
Approved by
GTU – Centre for Continuing Education (GTU-CCE)
On
“Clinical Research and Pharmacovigilance”

Sr. No.	CONTENTS
1	About GTU
2	About ROFEL Shri G. M. Bilakhia College of Pharmacy
3	About Course
4	Significance of Course
5	Objectives of Course

6	Outcomes of Course
7	Resource Person Profile
8	Date and session wise Course Content delivered
9	List of Participants
10	Session wise attendance of Participants
11	Evaluation Methodology
12	Result after Evaluation
13	Feedback from participants
14	Few Photographs of Course content delivery

1. About GTU

Gujarat Technological University is a premier academic and research institution which has driven new ways of thinking since its 2007 founding, established by the Government of Gujarat vide Gujarat Act No. 20 of 2007. Today, GTU is an intellectual destination that draws inspired scholars to its campus, keeping GTU at the nexus of ideas that challenge and change the world.

GTU is a State University with 486 affiliated colleges in its fold operating across the state of Gujarat through its FIVE zones at Ahmedabad, Gandhinagar, Vallabh Vidyanagar, Rajkot and Surat. The University caters to the fields of Engineering, Architecture, Management, Pharmacy and Computer Science. The University has about 4,00,000 students enrolled in a large number of Diploma, Under Graduate, Post Graduate programs along with the robust Doctoral program.

GTU has set up a Centre for Continuing Education (GTU-CCE) in the month of September 2019 with the objective of providing a platform for specialized short term certificate courses based on the current needs of companies.

2. About ROFEL Shri G. M. Bilakhia College of Pharmacy

ROFEL Shri G. M. Bilakhia College of Pharmacy is a modern temple of learning founded in 1999 by ROFEL Trust where quality education is more than a philosophy. It is one of the premier pharmacy college, imparting quality pharmaceutical education and training for more than two decades offering undergraduate and postgraduate courses in pharmacy. More than 1500 pharmacists (B.Pharm and M.Pharm graduates) of ROFEL now hold prominent positions in industry and academia, both in India and Abroad. The college is located in ROFEL Namdha campus which is about 1.5 km from Vapi Railway station and about 2 km from Vapi GSRTC bus stand.

ROFEL Shri G. M. Bilakhia College of Pharmacy is GTU affiliated college proposed to start the short term certificate course under GTU-CCE on “Pharmaceutical Quality Management system” with a view to provide knowledge on industrial concepts.

Dr. Ankit Merai and Dr. Chirag Desai Course coordinator working as Associate Professor in Department of Pharmacology had presented a proposal for course on Clinical Research and Pharmacovigilance to Advisory Committee of the Centre and approval to start the course was given by GTU-CCE centre after thorough scrutiny of the course proposal.

3. About Course

Course Name: “Clinical Research and Pharmacovigilance”

Duration: 36 Hours (Online mode via Google meet)

Course Commencing From: 19/03/2023 to 04/06/2023

(Saturday - Sunday from 9:30 am to 1:30 pm)

Registration Fees: 1800/- per candidate

Minimum Eligibility: D. Pharm, B.Pharm, M.Pharm (completed or pursuing)

Registration Link: <https://forms.gle/cgsrBu6X7KDN92Nu8>

Convener: Dr. Arindam Paul

Coordinators: 1. Dr. Ankit Merai

2. Dr. Chirag Desai

4. Significance of Course

- Everywhere, clinical trials are used to determine the safety and effectiveness of a chemical or biological product in relation to its effects on marks or a known disease process.
- Clinical trials that give information on the risks and benefits of the medicine are a driving force behind pharmacovigilance.
- Clinical research and pharmacovigilance seeks to determine if benefits outweigh dangers; if they do, drug producers take action to secure approval to commercialize the new medicine.
- Drug safety relies heavily on pharmacovigilance. Pharmaceutical firms can learn more about a drug's safety profile according to Pharmacovigilance (PV) analysis done during Phase I, Phase II, and Phase III clinical studies. If more research and development is required, this data may be utilized for that, or it can be provided to regulatory bodies to open up new markets.
- PV procedures used in clinical research as well as those carried out by consumers and medical experts can provide important information about the safety profile of pharmaceutical drugs.

5. Objective of Course

- To understand basis of pharmacology and pharmacy in clinical research.
- To understand and evaluate the novel signal (ADR) from the cases that have been reported.
- Analysis the benefit-risk ratio of some Commercially available drugs.
- The evidence-basis information on the pharmaceutical safety.
- To assist regulatory bodies in making decisions on the use of drugs.
- To reduce risk, it is important to inform diverse stakeholders on the safety of using medications.
- Generating expertise in pharmacovigilance operations.

6. Outcome of Course

On completion of this course, the participants will be able to:

- Get the knowledge on molecular clinical research, chemical research, forensic clinical research, etc.
- Get the Knowledge on Clinical trial compliance and quality assurance.
- Participants will get idea about Pharmacovigilance, ADR, regular-tions in pharmacovigilance.
- Participants will learn about herbal and medical devise vigilance. Knowledge on inspection and complains of Pharmacovigilance.

Placement Opportunities:

Candidate may pursue in Pharmaceutical, Biotechnological, Medical Device, Cosmetics, Natural health products and allied industries.

Candidate may hired as:

- ❖ Clinical research coordinator
- ❖ Pharmacovigilance data management associate
- ❖ Clinical research associate
- ❖ Pharmacovigilance associate
- ❖ Clinical data management associate and Clinical research monitor

7. Resource Person Profile

Sr. No.	Name	Designation & Work Place
1.	Dr. Shailendra Jha	HOD, Medical Research, Kokilaben Dhirubhai Ambani Hospital and Medical Research Institute, Mumbai
2.	Dr. Rikin Patel	Global Clinical Research Project Manager, Veeda Clinical Research Ltd, Ahmedabad
3.	Dr. Dipal Rana	Manager, Pharmacovigilance, Lupin Pvt. Ltd., Mumbai
4.	Dr. Manoj Swaminathan	Pharmacovigilance Expert, Mumbai
5.	Dr. Shivani Desai	Manager, Clinical Operations, Serum Institute, Pune

6.	Dr Kanav Khera	Dept of Pharmacy Practice, School of Pharmaceutical Science, Lovely Professional University, Punjab
7.	Dr. Pramod Pujari	Assistant general manager, Serum Institute of India Pvt Ltd. Pune
8.	Mr. Amish Gandhi	Pharmacovigilance Officer Team Lead, Ahmedabad, Gujarat
9.	Dr. Zankhana Atodaria	Associate Professor, ROFEL MBA, Vapi, Gujarat
10.	Miss. Saloni Desai	Senior Scientist, Latitude Pharmaceuticals Inc, California, USA
11.	Mr. Prit Desai	Pharmacovigilance Officer, Lambda Therapeutics Research Ltd., Ahmedabad
12.	Mrs. Saloni Desai	Safety Associate, IQVIA, Bangaluru, Karnataka

8. Date and Session wise Course Content Delivered

Sr. No.	Date/Time	Hours	Topic	Name of Resource Person
1	19/3/24	3	Fundamental of Clinical research regulation, Drug development process	Dr Rikin Patel
2	25/3/24	3	Documentation of CTA/NDA dossier, End point in clinical research, Recent advances in clinical research, Advancement in Contract research organization	Mr. Vijaybabu Mudaliar
3	26/3/23 16,22/4/23	8	Module 2/ Module 3	Dr Shailendra Jha
4	22,23/4/23	4	ICH and GCP guideline	Dr Kanav Khera
5	6/5/23	2	Argus Software	Mr. Amish Gandhi
6	7/5/23	2	Vaccination in PV	Dr. Shivani Desai

7	13/5/23	2	Intro PV	Dr. Pramod Pujari
8	14/5/23	2	Case Study	Dr. Deepal Rana
9	27/5/23	2	Case Study	Mr. Preet Desai
10	28/5/23	3	Bio-statistical Software	Dr. Zankhana Atodaria
11	3/6/23	3	Pharmacovigilance	Dr Manoj Swaminathan
12	4/6/23	2	Pharmacovigilance	Miss. Saloni Desai

9. List of Participants

A Short-term Certificate Course on Pharmaceutical Quality Management System (Batch-II) List of Participants	
Enrollment Number	Name of Participant
CCE01150001	AYUSHI DESAI
CCE01150002	Bharatia Rishi Hiren
CCE01150003	BRAHMBHATT DEV MAYANK
CCE01150004	CHHATARIYA NAFISHA ALIASGAR
CCE01150005	Dabhi Prachi Mansukhbhai
CCE01150006	Drashti C. Rana
CCE01150007	Gori Pooja Sureshbhai
CCE01150008	Harshita Sushil Kumar

CCE01150009	Harvi Bhatt
CCE01150010	Jiya Desai
CCE01150011	Joshi Urvi Pareshkumar
CCE01150012	Lakhatariya Krisaben Kantilal
CCE01150013	Mrs. Amita H. Patel
CCE01150014	Ms. MAHYAVANSHI DIVYA. R
CCE01150015	Ms. Mrunali A. Nemade
CCE01150016	Nikhil Kishanlal Khetan
CCE01150017	Nikita Dipakkukar Champaneri
CCE01150018	PANJWANI ANISHA MURADALI
CCE01150019	Panse Anuja Ravindra
CCE01150020	Paswan Praveen kumar
CCE01150021	Patel Aayushi Jayantibhai
CCE01150022	Patel Dhruvi Mehulbhai
CCE01150023	Patel hetvi vijaybhai
CCE01150024	Patel Krishna Natvarbhai
CCE01150025	Patel Shreya balubhai
CCE01150026	PAWAR JITUBHAI AMBUBHAI
CCE01150027	Prajapati Nishita Prakashbhai
CCE01150028	Prexa Manojbhai Tandel
CCE01150029	Purohit Kajal Dineshbhai

CCE01150030	Purohit Pinkikumari Shivilal
CCE01150031	Rana Dhruvil Ketan
CCE01150032	Rana Vanshika Devendra
CCE01150033	RATHOD PRAVINBHAI CHHAGANBHAI
CCE01150034	Rhutu Shah
CCE01150035	Rishabh jha
CCE01150036	Roy Hena Mansurali
CCE01150037	Sadhnakumari Chourasiya
CCE01150038	SAIF SHAIKH
CCE01150039	Shweta
CCE01150040	SINGH ANSIMA DEVENDRA
CCE01150041	Singh Shweta Vinod
CCE01150042	Sinha Neeta Dhananjay
CCE01150043	Sunita Arvindbhai Patel
CCE01150044	TANDEL JINAL NAVINBHAI
CCE01150045	Tiwari Pratibha Lalchand
CCE01150046	Vanshika jayeshbhai rana
CCE01150047	Vidhi Chandrakant Rana
CCE01150048	Vishva Kamalkumar Raval
CCE01150049	Yesha Dipakkumar Joshi
CCE01150050	Zil Raheshkumar Patel

10. Session wise attendance of participants

Enrollment Number	Name of Participant (As required on Certificate)	Attendance	
		Theory Session	Practical Session
CCE01150001	AYUSHI DESAI	100%	97%
CCE01150002	Bharatia Rishi Hiren	89%	93%
CCE01150003	BRAHMBHATT DEV MAYANK	89%	100%
CCE01150004	CHHATARIYA NAFISHA ALIASGAR	100%	100%
CCE01150005	Dabhi Prachi Mansukhbhai	95%	100%
CCE01150006	Drashti C. Rana	100%	97%
CCE01150007	Gori Pooja Sureshbhai	85%	95%
CCE01150008	Harshita Sushil Kumar	100%	100%
CCE01150009	Harvi Bhatt	100%	100%
CCE01150010	Jiya Desai	95%	93%
CCE01150011	Joshi Urvi Pareshkumar	100%	90%
CCE01150012	Lakhatariya Krisaben Kantilal	92%	93%
CCE01150013	Mrs. Amita H. Patel	100%	87%
CCE01150014	Ms. MAHYAVANSHI DIVYA. R	95%	100%
CCE01150015	Ms. Mrunali A. Nemade	100%	93%
CCE01150016	Nikhil Kishanlal Khetan	89%	78%
CCE01150017	Nikita Dipakkukar Champaneri	90%	85%
CCE01150018	PANJWANI ANISHA MURADALI	100%	100%

CCE01150019	Panse Anuja Ravindra	10%	10%
CCE01150020	Paswan Praveen kumar	90%	100%
CCE01150021	Patel Aayushi Jayantibhai	78%	80%
CCE01150022	Patel Dhruvi Mehulbhai	78%	100%
CCE01150023	Patel hetvi vijaybhai	100%	95%
CCE01150024	Patel Krishna Natvarbhai	89%	75%
CCE01150025	Patel Shreya balubhai	100%	100%
CCE01150026	PAWAR JITUBHAI AMBUBHAI	89%	100%
CCE01150027	Prajapati Nishita Prakashbhai	89%	93%
CCE01150028	Prexa Manojbhai Tandel	100%	100%
CCE01150029	Purohit Kajal Dineshbhai	85%	100%
CCE01150030	Purohit Pinkikumari Shivlal	100%	93%
CCE01150031	Rana Dhruvil Ketan	89%	95%
CCE01150032	Rana Vanshika Devendra	100%	93%
CCE01150033	RATHOD PRAVINBHAI CHHAGANBHAI	100%	93%
CCE01150034	Rhutu Shah	89%	100%
CCE01150035	Rishabh jha	85%	93%
CCE01150036	Roy Hena Mansurali	10%	10%
CCE01150037	Sadhnakumari Chourasiya	10%	10%
CCE01150038	SAIF SHAIKH	100%	100%
CCE01150039	Shweta	100%	100%
CCE01150040	SINGH ANSIMA DEVENDRA	89%	100%

CCE01150041	Singh Shweta Vinod	100%	100%
CCE01150042	Sinha Neeta Dhananjay	100%	100%
CCE01150043	Sunita Arvindbhai Patel	89%	100%
CCE01150044	TANDEL JINAL NAVINBHAI	90%	90%
CCE01150045	Tiwari Pratibha Lalchand	80%	85%
CCE01150046	Vanshika jayeshbhai rana	70%	85%
CCE01150047	Vidhi Chandrakant Rana	90%	95%
CCE01150048	Vishva Kamalkumar Raval	85%	84%
CCE01150049	Yesha Dipakkumar Joshi	72%	75%
CCE01150050	Zil Raheshkumar Patel	85%	90%

11. Session wise attendance of participants

Enrollment Number	Name of Participant (As required on Certificate)	Attendance	
		Theory Session	Practical Session
CCE01150001	AYUSHI DESAI	100%	97%
CCE01150002	Bharatia Rishi Hiren	89%	93%
CCE01150003	BRAHMBHATT DEV MAYANK	89%	100%
CCE01150004	CHHATARIYA NAFISHA ALIASGAR	100%	100%
CCE01150005	Dabhi Prachi Mansukhbhai	95%	100%
CCE01150006	Drashti C. Rana	100%	97%
CCE01150007	Gori Pooja Sureshbhai	85%	95%
CCE01150008	Harshita Sushil Kumar	100%	100%
CCE01150009	Harvi Bhatt	100%	100%
CCE01150010	Jiya Desai	95%	93%

CCE01150011	Joshi Urvi Pareshkumar	100%	90%
CCE01150012	Lakhatariya Krisaben Kantilal	92%	93%
CCE01150013	Mrs. Amita H. Patel	100%	87%
CCE01150014	Ms. MAHYAVANSHI DIVYA. R	95%	100%
CCE01150015	Ms. Mrunali A. Nemade	100%	93%
CCE01150016	Nikhil Kishanlal Khetan	89%	78%
CCE01150017	Nikita Dipakkukar Champaneri	90%	85%
CCE01150018	PANJWANI ANISHA MURADALI	100%	100%
CCE01150019	Panse Anuja Ravindra	10%	10%
CCE01150020	Paswan Praveen kumar	90%	100%
CCE01150021	Patel Aayushi Jayantibhai	78%	80%
CCE01150022	Patel Dhruvi Mehulbhai	78%	100%
CCE01150023	Patel hetvi vijaybhai	100%	95%
CCE01150024	Patel Krishna Natvarbhai	89%	75%
CCE01150025	Patel Shreya balubhai	100%	100%
CCE01150026	PAWAR JITUBHAI AMBUBHAI	89%	100%
CCE01150027	Prajapati Nishita Prakashbhai	89%	93%
CCE01150028	Prexa Manojbhai Tandel	100%	100%
CCE01150029	Purohit Kajal Dineshbhai	85%	100%
CCE01150030	Purohit Pinkikumari Shivilal	100%	93%
CCE01150031	Rana Dhruvil Ketan	89%	95%
CCE01150032	Rana Vanshika Devendra	100%	93%
CCE01150033	RATHOD PRAVINBHAI CHHAGANBHAI	100%	93%
CCE01150034	Rhutu Shah	89%	100%
CCE01150035	Rishabh jha	85%	93%
CCE01150036	Roy Hena Mansurali	10%	10%
CCE01150037	Sadhnakumari Chourasiya	10%	10%
CCE01150038	SAIF SHAIKH	100%	100%

CCE01150039	Shweta	100%	100%
CCE01150040	SINGH ANSIMA DEVENDRA	89%	100%
CCE01150041	Singh Shweta Vinod	100%	100%
CCE01150042	Sinha Neeta Dhananjay	100%	100%
CCE01150043	Sunita Arvindbhai Patel	89%	100%
CCE01150044	TANDEL JINAL NAVINBHAI	90%	90%
CCE01150045	Tiwari Pratibha Lalchand	80%	85%
CCE01150046	Vanshika jayeshbhai rana	70%	85%
CCE01150047	Vidhi Chandrakant Rana	90%	95%
CCE01150048	Vishva Kamalkumar Raval	85%	84%
CCE01150049	Yesha Dipakkumar Joshi	72%	75%
CCE01150050	Zil Raheshkumar Patel	85%	90%

12. Evaluation Methodology

Evaluation Scheme:

Sr. No.	Particular	Total Marks	Minimum Passing marks
1	Viva/MCQ (Internal)	40	16
2	Case study / Presentation / Viva (External)	60	24
Total		100	40

13. Result after Evaluation

Enroll ment Numb er	Name of Partici pant	Dr. Rikin Patel	Mr. VijayBabu Mudaliar	Dr. Shailendra Jha	Dr. Kanav Khera	Mr. Amish Gandhi	Dr. Shivani Desai	Dr. Pramod Pujari	Dr. Deepal Rana	Mr.Preet Desai	Dr. Zankhna Atodaria	Dr. Manoj Swami nathan	Miss. Saloni Desai
CCE0115001	AYUSHI DESAI	Good	Excellent	Excellent	Excellent	Excellent	Good	Good	Excellent	Good	Excellent	Excellent	Good

CCE01150002	Bharati Rishi Hiren	Good	Excellent	Excellent	Excellent	Excellent	Good	Good	Excellent	Good	Good	Good	Excellent
CCE01150003	BRAHMBHATT DEV MAYANK	Good	Excellent	Excellent	Good	Excellent	Good	Excellent	Excellent	Good	Good	Good	Excellent
CCE01150004	CHHATA RIYA ANAFISHA ALIAGAR	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent	Good	Excellent	Excellent	Excellent	Excellent	Excellent
CCE01150005	Dabhi Prachi Mansukhbhai	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent	Good	Excellent	Excellent	Excellent	Excellent
CCE01150006	Drashti C. Rana	Good	Good	Excellent	Good	Good	Good	Excellent	Good	Excellent	Good	Good	Good
CCE01150007	Gori Pooja Sureshbhai	Good	Good	Excellent	Excellent	Excellent	Excellent	Good	Excellent	Excellent	Excellent	Excellent	Excellent
CCE01150008	Harshita Sushil Kumar	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent
CCE01150009	Harvi Bhatt	Good	Good	Good	Excellent	Good	Excellent	Good	Excellent	Excellent	Excellent	Excellent	Good
CCE01150010	Jiya Desai	Good	Good	Excellent	Good	Good	Good	Good	Good	Excellent	Excellent	Excellent	Good
CCE01150011	Joshi Urvi Pareshkumar	Excellent	Excellent	Good	Good	Good	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent
CCE01150012	Lakhatariya Krisab	Good	Good	Good	Good	Good	Good	Excellent	Excellent	Good	Excellent	Excellent	Excellent

	en Kantilal												
CCE0 11500 13	Mrs. Amita H. Patel	Excell ent	Good	Excell ent	Excell ent	Excell ent	Exce llent	Excell ent	Exce llent	Exce llent	Exce llent	Excell ent	Excell ent
CCE0 11500 14	Ms. MAHY AVAN SHI DIVYA. R	Excell ent	Good	Good	Excell ent	Excell ent	Exce llent	Excell ent	Go od	Exce llent	Exce llent	Excell ent	Good
CCE0 11500 15	Ms. Mrunali A. Nemad e	Good	Good	Good	Excell ent	Good	Exce llent	Good	Exce llent	Go od	Go od	Good	Good
CCE0 11500 16	Nikhil Kishan lal Khetan		Excell ent		Excell ent	Excell ent	Go od	Good	Exce llent	Go od	Exce llent	Excell ent	Good
CCE0 11500 17	Nikita Dipakk ukar Champ aneri	Good	Excell ent	Good	Excell ent	Good	Exce llent	Excell ent	Exce llent	Exce llent	Exce llent	Excell ent	Excell ent
CCE0 11500 18	PANJ WANI ANISH A MURA DALI	Excell ent	Good	Excell ent	Good	Good	Go od	Good	Go od	Go od	Exce llent	Excell ent	Good
CCE0 11500 19	Panse Anuja Ravind ra	Excell ent	Good	Good	Excell ent	Excell ent	Exce llent	Excell ent	Go od	Go od	Exce llent	Excell ent	Good
CCE0 11500 20	Paswa n Pravee n kumar	Good	Good	Excell ent	Excell ent	Excell ent	Go od	Excell ent	Exce llent	Exce llent	Exce llent	Excell ent	Excell ent
CCE0 11500 21	Patel Aayush i	Excell ent	Excell ent	Excell ent	Excell ent	Excell ent	Exce llent	Excell ent	Go od	Go od	Go od	Good	Excell ent

	Jayanti bhai												
CCE0 11500 22	Patel Dhruvi Mehulb hai	Excell ent	Good	Good	Good	Good	Good	Good	Good	Good	Good	Good	Good
CCE0 11500 23	Patel hetvi vijaybh ai	Excell ent	Excellen t	Excell ent	Excell ent	Excell ent	Excell ent	Good	Excell ent	Excell ent	Excell ent	Excell ent	Good
CCE0 11500 24	Patel Krishn a Natvar bhai	Excell ent	Excellen t	Excell ent	Excell ent	Excell ent	Good	Excell ent	Excell ent	Excell ent	Excell ent	Excell ent	Excell ent
CCE0 11500 25	Patel Shreya balubh ai	Good	Excellen t	Excell ent	Good	Excell ent	Good	Good	Excell ent	Good	Excell ent	Good	Excell ent
CCE0 11500 26	PAWA R JITUB HAI AMBU BHA	Good	Good	Excell ent	Good	Good	Good	Good	Excell ent	Good	Excell ent	Excell ent	Excell ent
CCE0 11500 27	Prajap ati Nishita Prakas hbhai	Good	Good	Excell ent	Excell ent	Excell ent	Excell ent	Excell ent	Excell ent	Excell ent	Excell ent	Excell ent	Good
CCE0 11500 28	Prexa Manojb hai Tandel	Excell ent	Excellen t	Good	Fair	Fair	Fair	Excell ent	Excell ent	Excell ent	Good	Good	Good
CCE0 11500 29	Purohit Kajal Dinesh bhai	Excell ent	Excellen t	Excell ent	Excell ent	Good	Excell ent	Fair	Excell ent	Good	Excell ent	Excell ent	Excell ent
CCE0 11500 30	Purohit Pinkiku mari Shivlal	Good	Excellen t	Excell ent	Excell ent	Excell ent	Excell ent	Excell ent	Excell ent	Excell ent	Excell ent	Excell ent	Excell ent
CCE0 11500	Rana Dhruvil	Excell ent	Excellen t	Excell ent	Excell ent	Excell ent	Excell ent	Excell ent	Excell ent	Good	Excell ent	Excell ent	Excell ent

31	Ketan													
CCE0 11500 32	Rana Vanshi ka Deven dra	Good	Excellent	Excellent	Excellent	Good	Good	Fair	Excellent	Excellent	Excellent	Fair	Excellent	
CCE0 11500 33	RATH OD PRAVI NBHAI CHHA GANB HAI	Good	Good	Excellent	Fair	Good	Excellent	Excellent	Excellent	Fair	Good	Good	Good	
CCE0 11500 34	Rhutu Shah	Good	Good	Excellent	Excellent	Good	Good	Good	Good	Good	Excellent	Excellent	Good	
CCE0 11500 35	Rishab h jha	Excellent	Excellent	Good	Good	Good	Good	Good	Good	Good	Good	Good	Good	
CCE0 11500 36	Roy Hena Mansur ali	Good	Good	Good	Good	Good	Good	Good	Good	Good	Good	Good	Good	
CCE0 11500 37	Sadhn akumar i Choura siya	Good	Good	Good	Good	Good	Good	Good	Good	Good	Good	Good	Good	
CCE0 11500 38	SAIF SHAIK H	Excellent	Excellent	Good	Good	Good	Good	Excellent	Excellent	Good	Good	Excellent	Good	
CCE0 11500 39	Shweta	Good	Excellent	Excellent		Excellent	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent	
CCE0 11500 40	SINGH ANSIM A DEVE NDRA	Excellent	Good	Excellent	Good	Excellent	Excellent	Good	Good	Excellent	Good	Excellent	Excellent	
CCE0 11500 41	Singh Shweta Vinod	Excellent	Good	Excellent	Excellent	Excellent	Excellent	Excellent	Good	Good	Excellent	Excellent	Good	
CCE0 11500	Sinha Neeta	Excellent	Good	Fair	Good	Good	Good	Excellent	Excellent	Excellent	Good	Fair	Excellent	

42	Dhana njay												
CCE0 11500 43	Sunita Arvind bhai Patel	Good	Excellent	Good	Excellent	Excellent	Good	Excellent	Good	Excellent	Excellent	Excellent	Excellent
CCE0 11500 44	TAND EL JINAL NAVIN BHAI	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent	Good	Excellent	Excellent	Excellent	Excellent	Excellent
CCE0 11500 45	Tiwari Pratibh a Lalcha nd	Good	Excellent	Good	Excellent	Good	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent
CCE0 11500 46	Vanshi ka jayesh bhai rana	Excellent	Excellent	Excellent	Fair	Excellent	Excellent	Excellent	Excellent	Good	Excellent	Good	Excellent
CCE0 11500 47	Vidhi Chandr akant Rana	Excellent	Good	Excellent	Good	Good	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent
CCE0 11500 48	Vishva Kamalk umar Raval	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent	Good	Excellent	Excellent	Excellent
CCE0 11500 49	Yesha Dipakk umar Joshi	Good	Excellent	Good	Excellent	Excellent	Excellent	Excellent	Good	Excellent	Excellent	Excellent	Excellent
CCE0 11500 50	Zil Rahes hkumar Patel	Excellent	Excellent	Fair	Excellent	Good	Excellent	Good	Excellent	Excellent	Excellent	Good	Excellent

14. Few Photographs of Course content delivery

1. Lecture delivered by Dr Rikin Patel

The screenshot shows a Google Meet interface. The main window displays a presentation slide with the following content:

- GTU Logo
- Index**
- ✓ Introduction of Clinical Research
- ✓ Overview of Drug Discovery & Development
- ✓ Overview of Drug Discovery
- ✓ Overview of Drug Development
- ✓ Documents in Clinical Research
- ✓ Conclusion

The slide also includes a 'Stop Annotating' button and a page number '3'. The bottom of the slide reads '10:19 AM | Module 1 Taken by Dr Rikin Patel'. The right sidebar shows a grid of participants: rikin patel (active), Saif Shaikh, Dr. Ankit Merai, Dhruvil Rana, Prexa Tandel, patel sunita, 45 others, and You.

2. Lecture taken by Mr. Vijaybabu Mudaliar

The screenshot shows a Google Meet interface. The main window displays a presentation slide with the following content:

- Patterned background with blue and white circles.
- CTA /NDA DOSSIER FILING**
- By Mr. Vijaybabu K. Mudaliar

The bottom of the slide reads '10:03 AM | Module 1 Clinical Research and Pharmaco...'. The right sidebar shows a grid of participants: Vijay M (active), Dr. Ankit Merai, Amita Patel, Pooja Gori, Dhruvil Rana, chirag desai, 36 others, and You.

3. Lecture taken by Dr. Sailendra Jha

The screenshot shows a Google Meet interface. The main content area displays a slide titled "Molecular Diagnostic" with the following bullet points:

- **Treatment**
 - Some of a patient's **single nucleotide polymorphisms**—slight differences in their DNA—can help predict how quickly they will metabolise particular drugs; this is called **pharmacogenomics**. For example, the enzyme **CYP2C19** metabolises several drugs, such as the anti-clotting agent **Clopidogrel**, into their active forms. Some patients possess polymorphisms in specific places on the **2C19** gene that make **poor metabolisers** of those drugs.
- **Infectious disease**
 - Molecular diagnostics are used to identify infectious diseases such as **influenza virus**; or specific strains such as **H1N1 virus** or **SARS-CoV-2**.
- **Disease risk management**
 - A patient's genome may include an **inherited** or **random mutation** which affects the probability of developing a disease in the future. For example, **Lynch syndrome** is a **genetic disease** that predisposes patients to **colorectal** and other cancers; early detection can lead to close monitoring that improves the patient's chances of a good outcome. **Cardiovascular risk** is indicated by biological markers and screening can measure the risk that a child will be born with a genetic disease such as **Cystic fibrosis**.
- **Cancer Detection**

The presenter is identified as "Shailendra Jha is presenting". The bottom of the screen shows a toolbar with icons for mute, video, chat, and other meeting controls. The time is 10:13 AM and the meeting title is "Module 2 Clinical Research and Pharmaco...".

4. Lecture Taken by Dr. Kanav Khera

The screenshot shows a Google Meet interface. The main content area displays a slide with the following text:

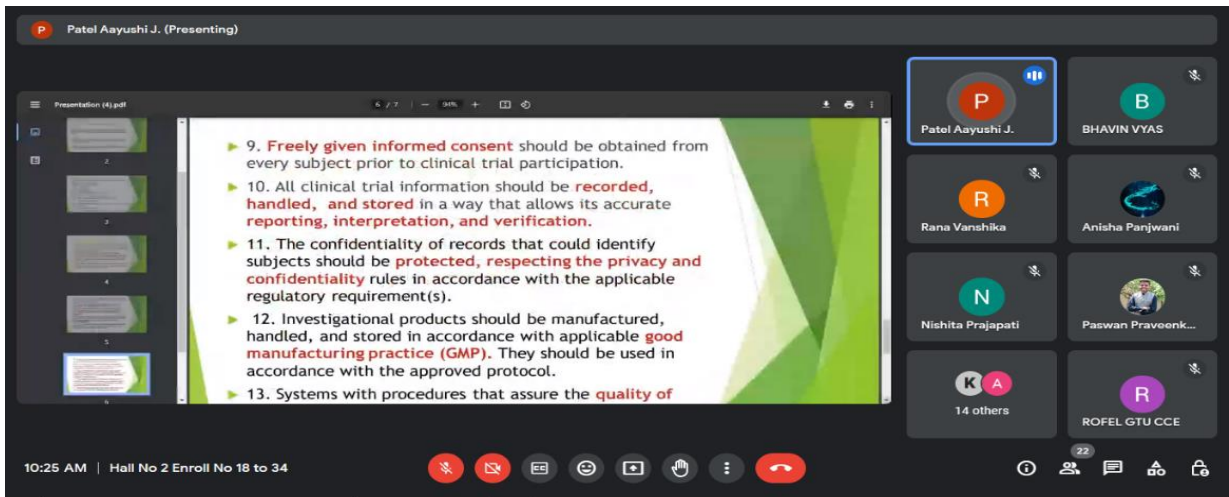
LOVELY PROFESSIONAL UNIVERSITY
Transforming Education Transforming India

Basic of Clinical Research ICH-GCP GUIDELINES E6

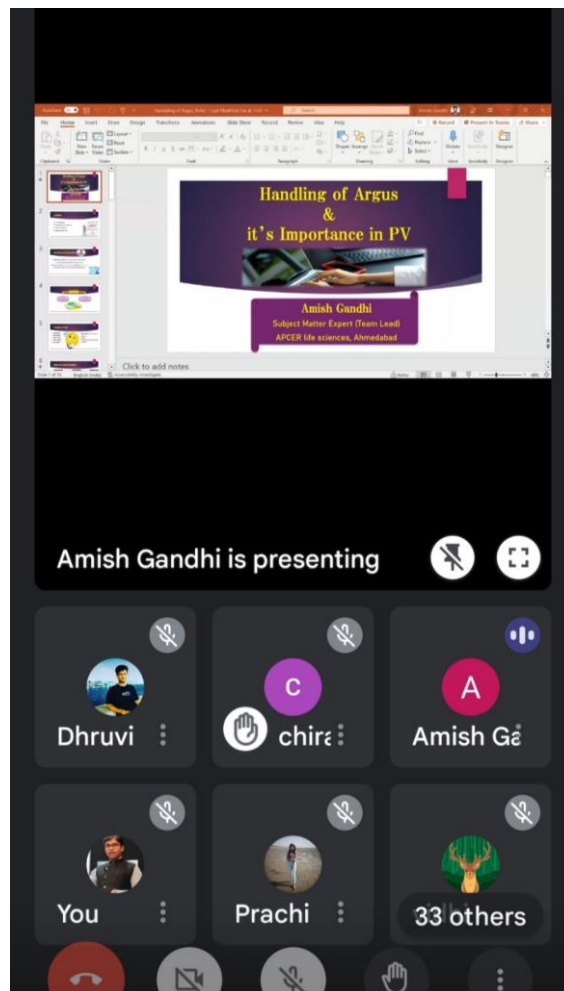
Dr Kanav KHERA
Mpharm, MBA, PhD
Professor, Dept of Pharmacy Practice/Pharmacology
School of Pharmaceutical Sciences
Lovely Professional University, Punjab-India

The presenter is identified as "Dr. Kanav Khera is presenting". The bottom of the screen shows a toolbar with icons for mute, video, chat, and other meeting controls. The time is 10:39 AM and the meeting title is "ICH and GCP Guideline".

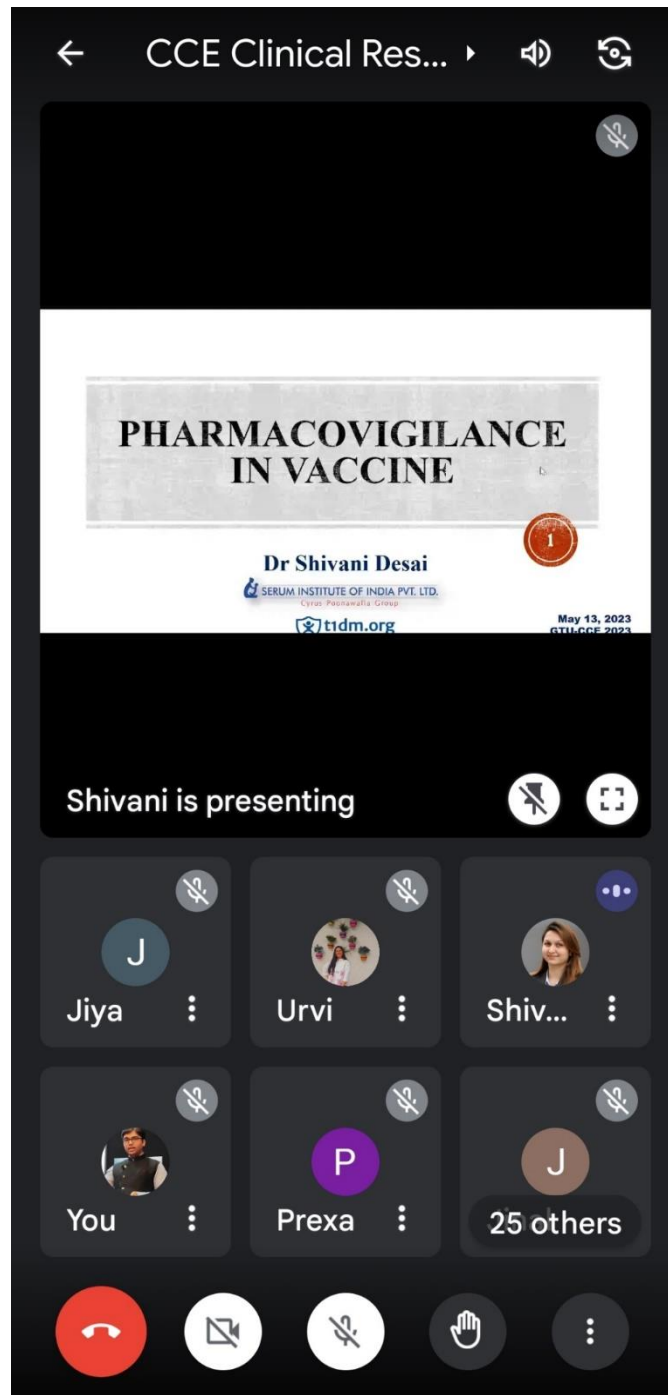
5. Lecture delivered by Dr. Pramod Pujari



6. Lecture delivered by Mr. Amish Gandhi



7. Lecture taken by Dr. Shivani Desai



8. Lecture taken by Miss. Saloni Desai.

The screenshot shows a Zoom meeting interface. At the top, the title bar reads "CCE Clinical Res..." with navigation icons. The main content is a presentation slide with the following text:

Drug Dictionary and Coding in Pharmacovigilance
GTU-Centre For Continuing Education (GTU-CCE) Short Term Certificate Course
On
"CCE Clinical Research And Pharmacovigilance"
at
Rofel Shree G M Bilakhia College of Pharmacy, Vapi

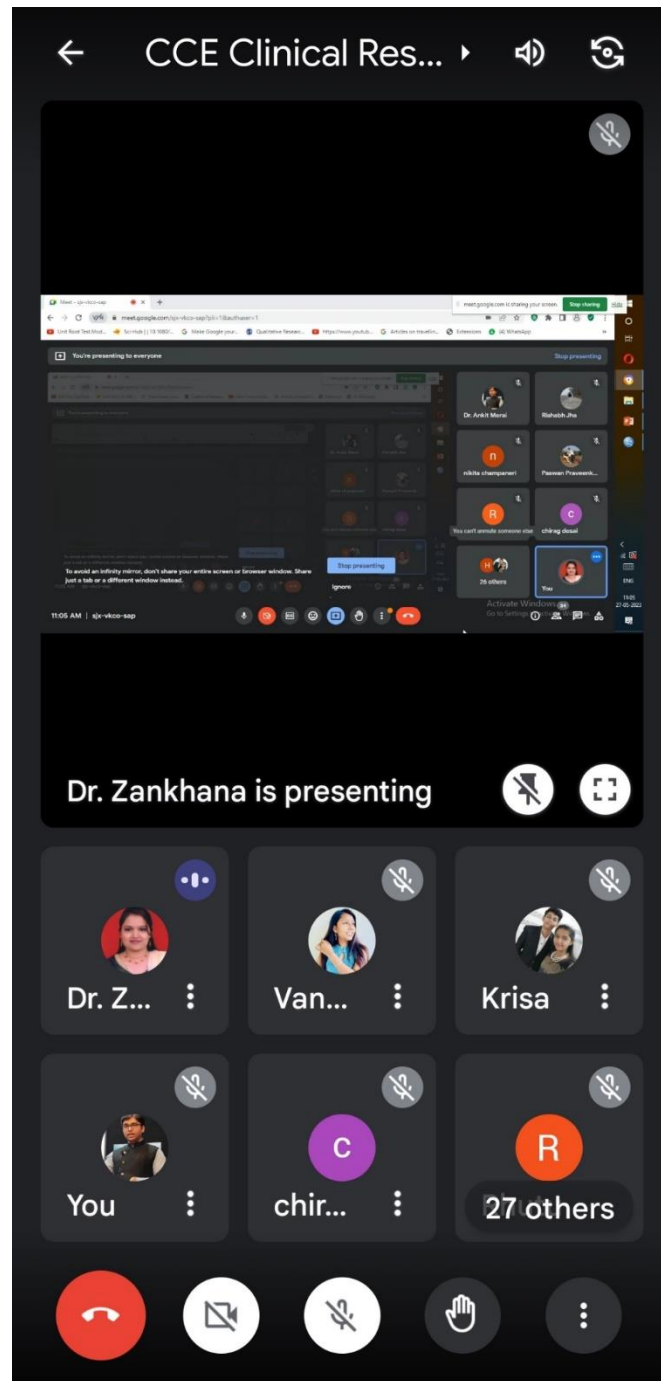
By:
Saloni Desai
Senior Scientist
Latitude Pharmaceuticals Inc., California, USA

Below the slide, the Zoom interface shows "Saloni is presenting" with icons for mute and video. The participant grid includes:

- chir... (muted)
- Saloni (presenting)
- Jinal (muted)
- You (muted)
- Kris... (muted)
- 28 others (highlighted with a blue border)

The bottom navigation bar contains icons for end call, chat, mute, hand raise, and more options.

9. Lecture taken by Dr Zankhana Atodaria



10. Lecture taken by Dr. Deepal Rana

← CCE Clinical Res... ▶ 🔊 🔄

ICSR criteria

Identifiable Patient	Identifiable Reporter	Suspect Drug	Adverse Event

Deepal Rana is presenting 🔊 📺

vidhi : chir... : Mru... :

You : Dee... : 35 others

11. Lecture taken by Mr. Preet Desai

The image shows a Zoom meeting interface. At the top, a slide titled "Case processing" is displayed on a light yellow background. The slide contains a bulleted list of items:

- Report type
- Reporter information
- Patient information
- Patient history
- Drug details-(WHO Dictionary)
- Event coding – Meddra (PT, LLT, HT)
- Laboratory tests code

Below the slide, a black bar indicates "prit is presenting" on the left. On the right side of this bar are two icons: a microphone with a slash through it (muted) and a square with four arrows pointing outwards (fullscreen).


Below the black bar is a grid of six participant tiles. Each tile contains a circular profile picture, a name, and a microphone icon. The tiles are:

- Top-left: "prit" with a profile picture of a man in a plaid shirt. A blue microphone icon is in the top right corner.
- Top-middle: "Ayushi" with a purple circle containing the letter "A". A grey microphone icon with a slash is in the top right corner.
- Top-right: "Amita" with a teal circle containing the letter "A". A grey microphone icon with a slash is in the top right corner.
- Bottom-left: "You" with a profile picture of a man in a dark vest. A grey microphone icon with a slash is in the top right corner.
- Bottom-middle: "harvi" with a profile picture of a woman. A grey microphone icon with a slash is in the top right corner.
- Bottom-right: "34 others" with a profile picture of a woman. A grey microphone icon with a slash is in the top right corner.


12. Lecture taken by Mr. Amish Gandhi

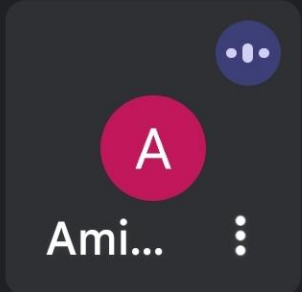
WHY ARGUS

- ▶ Ensures Global Regulatory compliance.
- ▶ Provide a strong technical ability to mine the data with epidemiologic focus
- ▶ Offers Better Data Insights and Faster decision making.
- ▶ Integrates Safety and Risk Management.




Amish Gandhi is presenting

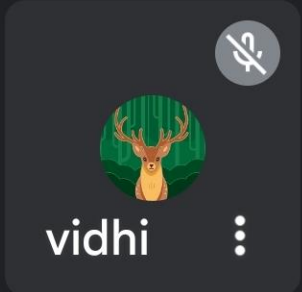




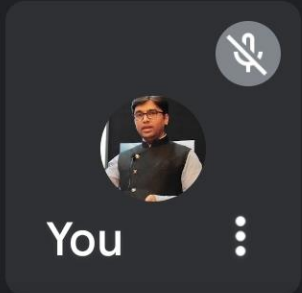
Ami... ⋮




Prac... ⋮




vidhi ⋮



You ⋮



Urvi ⋮



35 others