SAROJINI NAIDU VANITA PHARMACY MAHA VIDYALAYA (Co-Ed.)
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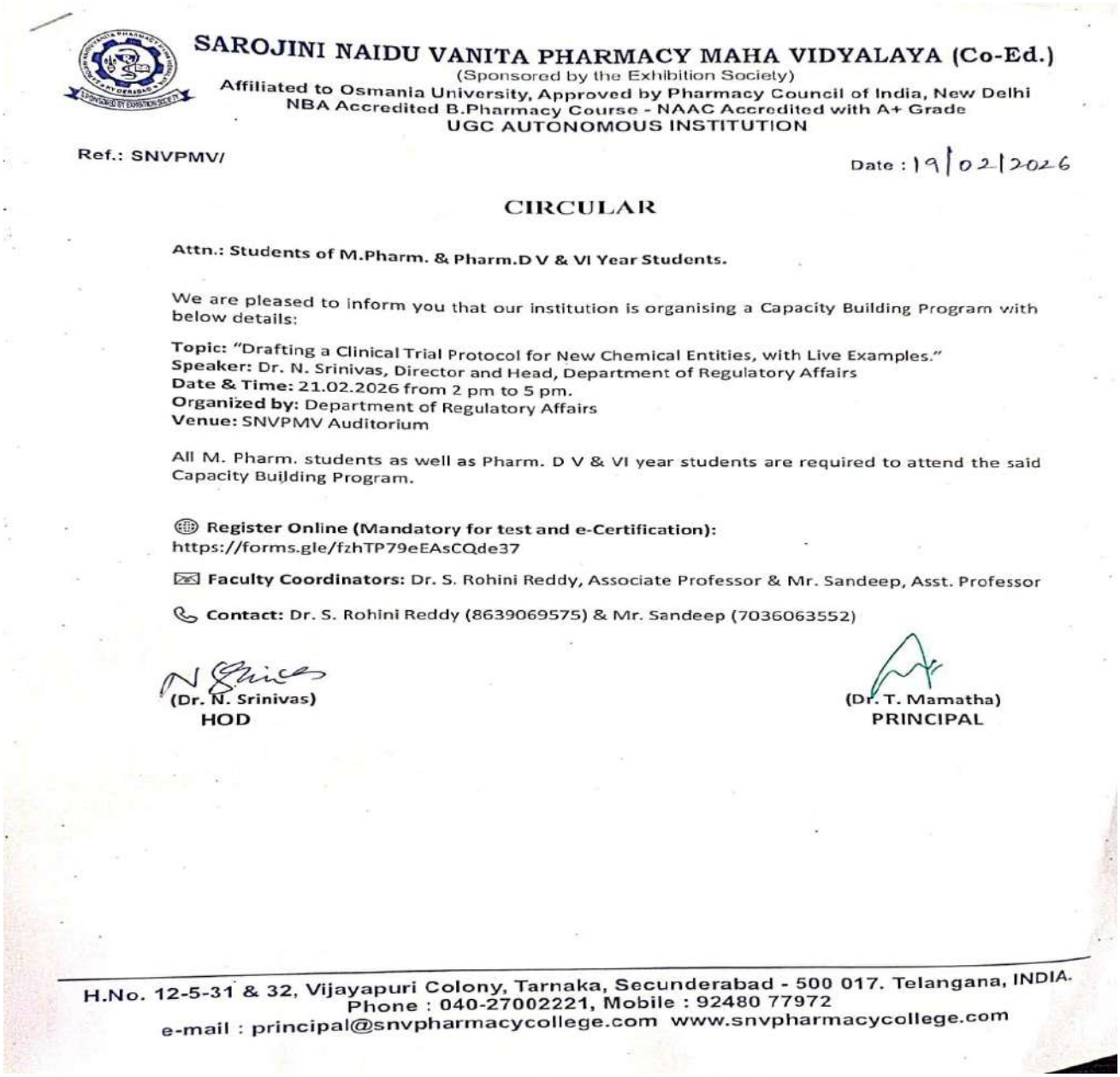
NBA Accredited B. Pharmacy Course, Accredited A+ grade by NAAC

REPORT ON DRAFTING A CLINICAL TRIAL PROTOCOL FOR NEW CHEMICAL ENTITIES WITH LIVE EXAMPLES

Date & Time – 21st Feb, 2026 at 2.00 PM



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Ref.: SNVPMV/

Date : 19/02/2026

CIRCULAR

Attn.: Students of M.Pharm. & Pharm.D V & VI Year Students.

We are pleased to inform you that our institution is organising a Capacity Building Program with below details:

Topic: "Drafting a Clinical Trial Protocol for New Chemical Entities, with Live Examples."
Speaker: Dr. N. Srinivas, Director and Head, Department of Regulatory Affairs
Date & Time: 21.02.2026 from 2 pm to 5 pm.
Organized by: Department of Regulatory Affairs
Venue: SNVPMV Auditorium

All M. Pharm. students as well as Pharm. D V & VI year students are required to attend the said Capacity Building Program.

Register Online (Mandatory for test and e-Certification):
https://forms.gle/fzhTP79eEAsCQde37

Faculty Coordinators: Dr. S. Rohini Reddy, Associate Professor & Mr. Sandeep, Asst. Professor

Contact: Dr. S. Rohini Reddy (8639069575) & Mr. Sandeep (7036063552)

(Dr. N. Srinivas)
HOD

(Dr. T. Mamatha)
PRINCIPAL

H.No. 12-5-31 & 32, Vijayapuri Colony, Tarnaka, Secunderabad - 500 017. Telangana, INDIA.
Phone : 040-27002221, Mobile : 92480 77972
e-mail : principal@snvpharmacycollege.com www.snvpharmacycollege.com

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Teaching Staff

19.02.2026

Capacity Building Program "Drafting a Clinical Trial Protocol for New Chemical Entities, with Live Examples." on 21.02.2026

Sl.No	Faculty Name	Designation	Signatures
1	Dr.N.Srinivas	Professor & Director	
2	Dr.T.Mamatha	Professor & Principal	
3	Dr.B.Haarika	Professor & Vice-Principal	
4	Dr.S.Hemalatha	Professor & HOD	
5	Dr.S.Anuradha Bai	Professor & HOD	
6	Dr.T.Venu	Professor & HOD	
7	Dr.Vivek Sagar	Professor & HOD	
8	Dr. B. Chandra Shekar Reddy	Professor & HOD	
9	Smt.R.V.S.Latha Sree	Associate Professor	
10	Dr.K.Neelima	Associate Professor	
11	Dr.B. Siva Jyothi	Associate Professor	
12	Dr. S.Rohini Reddy	Associate Professor	
13	Dr. CH.Shanthi Priya	Associate Professor	
14	Dr.K.Vinutha	Associate Professor	
15	Dr. K.R.V.S. Chaitanya	Associate Professor	
16	Dr. M. Sreekanth	Associate Professor & HOD	
17	Dr. P. Ravi Kumar	Associate Professor & HOD	
18	Dr. T. Vani	Associate Professor	
19	Mrs. K. Geethanjali	Associate Professor	
20	Dr.Leemol Shaju	Sr. Assistant Professor	
21	Dr.Ch.Bhargavi	Assistant Professor	
22	Smt.G.Srilalitha	Assistant Professor	
23	Smt.N.Indira Rani	Assistant Professor	
24	Smt.S.Muni Sireesha	Assistant Professor	
25	Smt. P.M.Sameera	Assistant Professor	
26	Ms.S.Divya	Assistant Professor	
27	Dr.Akaram Sujala	Assistant Professor	
28	Smt.Azmeera Jyothi	Assistant Professor	
29	Smt.P.Kavitha Babu Rao	Assistant Professor	
30	Mrs. A.Shailaja	Assistant Professor	

31	Mrs.Jutta Swathi	Assistant Professor	
32	Dr Jithender	Assistant Professor	
33	Dr. V. Santhoshini	Assistant Professor	
34	Dr. Hadiya Iram	Assistant Professor	
35	Ms. P. Sri Varsha	Assistant Professor	
36	Dr.M. Shiva Rama Krishna	Assistant Professor	
37	Mrs. J. Sarika	Assistant Professor	
38	Mr. D. Suresh	Assistant Professor	
39	Mrs. P. Rajyalakshmi Devi	Assistant Professor	
40	Mrs. Samreen	Assistant Professor	
41	Mr. K. Sandeep	Assistant Professor	
42	Mrs. Ritu Jain	Assistant Professor	
43	Mrs. J. Sunayana	Assistant Professor	
44	Ms. N. Rojaramani	Assistant Professor	

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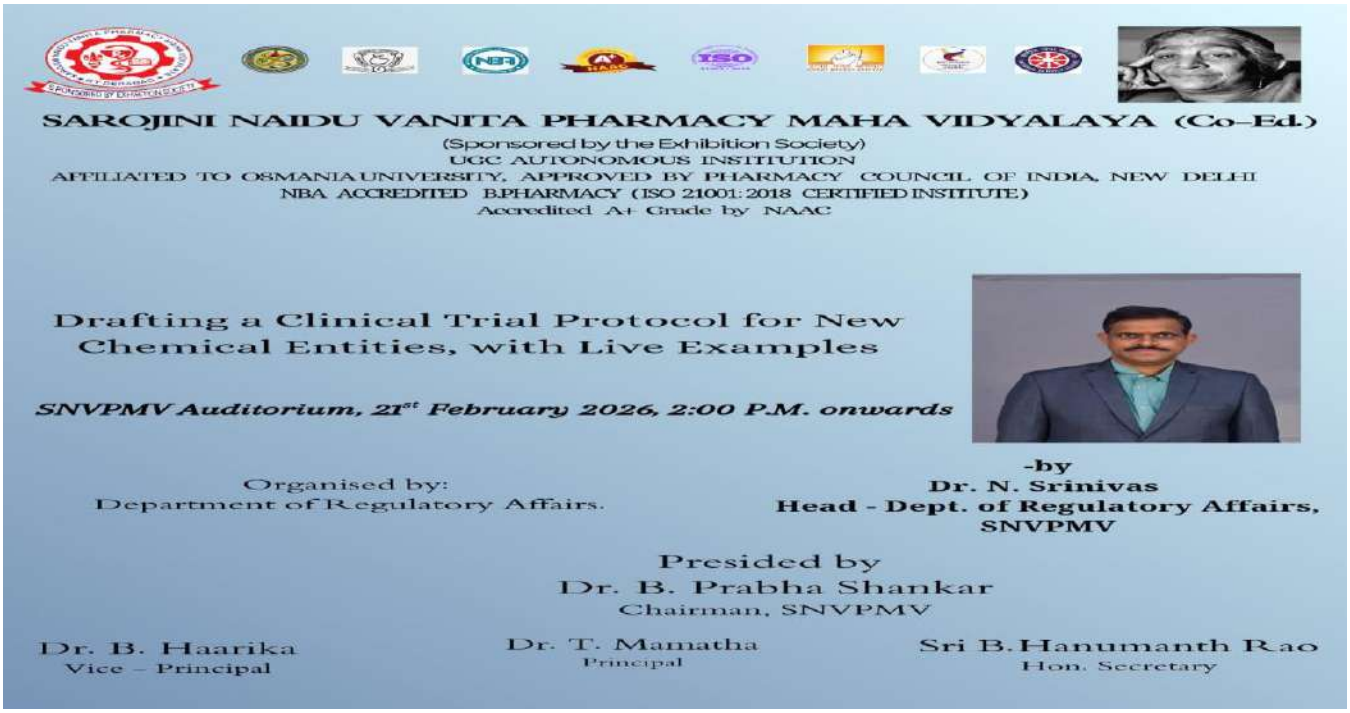

This workshop was conducted on 23/2/26

Time: 2:00 PM – 4:30 PM

All the students of M Pharmacy of various departments have attended the workshop and gained valuable insights into the various aspects of clinical trial and how a protocol can be drafted for a new chemical entity. Dr. N. Srinivas, Director and HOD department of Regulatory Affairs have taken the initiative of conducting the workshop and guiding students for the drafting of clinical trial protocol.

Clinical research involving human participants must be scientifically justified, ethically conducted, and properly documented. The foundation of any clinical study is the research protocol. A clinical trial protocol is a detailed document that describes the objectives, design, methodology, statistical considerations, and organization of a trial. According to ICH-GCP guidelines, Good Clinical Practice is an international ethical and scientific quality standard for designing, conducting, recording, and reporting trials involving human subjects. A well-developed protocol ensures participant safety, data integrity, and regulatory compliance.

The purpose of a research protocol is to standardize study procedures, guide the research team, and provide a reviewable document for approvals from Institutional Ethics Committees (IEC), Institutional Review Boards (IRB), regulatory authorities, and funding agencies. It clearly explains why the study is being conducted, what interventions will be performed, who the target population is, where the study will take place, and when assessments will occur. Proper protocol development also helps in time planning, budgeting, and avoiding unnecessary amendments during the study.

A standard clinical protocol includes general information such as protocol title, version, investigator details, sponsor information, and study sites. It contains background and rationale supported by scientific literature, clearly defined primary and secondary objectives, detailed study design, eligibility criteria, treatment plans, safety monitoring procedures, statistical analysis plan, and ethical considerations. Inclusion and exclusion criteria ensure proper selection of participants to maintain scientific validity and patient safety. Safety monitoring includes documentation and reporting of adverse events (AEs) and serious adverse events (SAEs),

along with predefined stopping rules. Statistical analysis plans are developed in advance to determine sample size, power, and appropriate analytical models.

The principles of multifactorial risk management are further illustrated by the Steno-2 Study, which evaluated intensive treatment strategies in patients with Type 2 Diabetes and micro albuminuria. This long-term randomized study demonstrated that aggressive management of blood glucose, blood pressure, cholesterol, and lifestyle factors significantly reduced cardiovascular events and delayed complications. The findings proved that early and comprehensive intervention can significantly improve long-term health outcomes.Similarly, the D4C Trial focused on improving diabetes management through a cluster-randomized implementation strategy in India. This large-scale study assessed the effectiveness of team-based care supported by a Clinical Decision Support System (CDSS). By integrating digital algorithms into clinical practice, the study aimed to improve control of HbA1c, systolic blood pressure, and LDL cholesterol. The results emphasized the importance of structured healthcare delivery systems in reducing cardiovascular risk in diabetic populations.

The study involved adults aged 30–65 years and utilized a standardized questionnaire assessing age, waist circumference, physical activity, and family history. Participants identified as high risk underwent capillary blood glucose testing. Individuals with elevated readings were referred to nearby government hospitals for further evaluation. Ethical safeguards included written informed consent, confidentiality through coded data collection, use of sterile equipment, and compliance with ICMR ethical guidelines. This project highlighted the role of pharmacy students in preventive public health initiatives.

In addition, a multi center retrospective case-control study was proposed to evaluate lung cancer risk across multiple modifiable and environmental factors. The study design included histopathologically confirmed lung cancer cases and matched controls from similar geographic areas. Risk factors such as smoking (measured in pack-years), alcohol consumption, obesity (BMI), hypertension, diabetes, and environmental pollution exposure were assessed using a standardized questionnaire. Statistical analysis involved calculation of odds ratios and multivariate logistic regression to adjust for confounding variables. This epidemiological approach allows quantification of independent and synergistic effects of various risk factors on lung cancer incidence.

Overall, the preparation and implementation of structured clinical protocols are essential for conducting scientifically valid and ethically sound research. From controlled Phase III clinical trials to community screening programs and epidemiological case-control studies, each research design requires meticulous planning, proper documentation, statistical rigor, and ethical compliance. Effective protocol development not only ensures regulatory approval but also protects participant safety and enhances the credibility of research outcomes. Properly designed studies contribute significantly to evidence-based medicine, public health advancement, and improved patient care.

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Topic: Drafting a clinical trial protocol for new chemical entities with live examples

ORGANIZED BY DEPARTMENT OF REGULATORY AFFAIRS

ATTENDANCE SHEET

S.No	NAME OF THE STUDENT	YEAR	SIGNATURE
1.	Ch. Bhuvana	M.pharm RA (1st yr)	
2.	C. Pragitha	"	
3.	V. Nikitha	"	V. Nikitha.
4.	M. Dedhipya	"	
5.	K. Lakshmi Priya	"	K. L. Priya
6.	V. Aashritha	"	
7.	M. Anandhini	"	Nandu
8.	A. Keerthi	"	Keerthi
9.	K. Manasa	M.pharm Cardio (1st yr)	Manasa
10.	Bhavishya	"	Bhavishya
11.	Tejaswini	"	Tejaswini
12.	Kavya	"	Kavya
13.	Vasanthi	M. pharm (RA) (1st yr)	Vasanthi
14.	Amena	M. pharmaceutics (1st yr)	Amena
15.	Ayesha	"	Ayesha
16.	Haseni	"	Haseni
17.	Praveena	"	Praveena
18.	Keerthi	"	Keerthi
19.	Vidyakshitha	M. Pharm RA	
20	Dhanthoni Das	"	
21	Sai Keerthana	"	
22	Akanksha	"	
23	Shriya	"	
24	Bhavya	"	
25	Rishitha	"	
26	Ruchitha	"	

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ATTENDANCE SHEET

S.No	NAME OF THE STUDENT	YEAR	SIGNATURE
1.	A. Hari kart-hik	M.Ph (cdraq) Ist yr	
2.	B. Ram	m.ph (QA) I st yr	
3.		M.Pharm (QA) I st yr	
4	P. Abhishek	M.Ph (QA) I st yr	
5	K Akhil varun	M.Ph (PA) I st yr	
6	SK Rizwan	M. Ph (Co) I st yr	
7	A. Keerthi	M.Ph (Pharmacology) I st yr	
8	K. Sravya sree	M.ph Cology I st yr	
9	M. Kavya	"	
10	K. Ramu	"	
11	A. Hannah	M.Pharm (RA) 2nd yr	
12.	S. Sai Sree	"	
13.	V. Laya Sree	M.Ph Analysis I st yr	
14.	M. komalika	MPAnalysis I st yr	
15.	P. Srija	MPAnalysis I st yr	
16.	M. Rohini	MPAnalysis I st yr	
17.	K. Sudha Rani	M.Ph (Pharmacology) I st yr	
18	B. Pallavi	M.pharm (RA) I st yr	
19.	B. Keerthi	M.pharm Centics I yr	
20.	D. Hareni	"	
21.	Raveena Gayathri	"	

IMPACT

The workshop conducted for all M. Pharmacy students of various departments had a significant academic and professional impact by enhancing their understanding of clinical trials and protocol development. Under the guidance of Dr. N. Srinivas, Director and Head of the Department of Regulatory Affairs, students gained comprehensive knowledge about drafting clinical trial protocols for new chemical entities in accordance with ICH-GCP guidelines. The session strengthened their awareness of ethical principles, regulatory requirements, informed consent procedures, safety monitoring, and proper documentation practices necessary for conducting scientifically valid and ethically sound research. By discussing landmark studies such as the Steno-2 Study and the D4C Trial, students were exposed to real-world examples demonstrating how structured protocols and multifactorial intervention strategies improve long-term health outcomes and reduce cardiovascular risk. The inclusion of community-based diabetes screening initiatives and a proposed multi center case-control study on lung cancer further broadened their understanding of epidemiological research, statistical analysis, and public health responsibilities.

OUTCOME

As an outcome, students developed the competency to design and draft well-structured clinical trial protocols that ensure participant safety, data integrity, and regulatory compliance. They are now better prepared for careers in clinical research, regulatory affairs, Pharmacovigilance, and the pharmaceutical industry. The workshop strengthened their ability to apply evidence-based medicine principles, plan research systematically, and implement ethical safeguards in human studies. Overall, the program laid a strong foundation for future research activities, dissertation work, and professional practice, enabling students to contribute effectively to clinical research excellence and public health advancement.

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