A report on

One Day Virtual Conference on "Challenges in the Conduct of Clinical Trials in India- Skills Required for Pharmacy Graduates": April 16, 2021

Organized by: Sarojini Naidu Vanita Pharmacy Maha Vidyalaya (SNVPMV)

In Association with: Indian Pharmaceutical Association, Telangana state branch.

Sarojini Naidu Vanita Pharmacy Maha Vidyalaya (SNVPMV) has conducted one-day virtual conference on the theme 'Challenges in the conduct of clinical trials in India- skills required for pharmacy graduates' on 16thApril 2021, from 10 am to 5 pm. SNVPMV has always made a continuous and persistent effort to train the pharma community on the latest trends in various thrust areas.

The virtual conference was started with an invocation to almighty by a prayer song by Ms Apoorva, a student of III-year B. Pharmacy. This one-day webinar was hosted by Ms. Poojitha and Ms PushpaSri, students of Pharm.D V year, Malik Kainat of IV-year B.Pharmacy, and Ms Rachna of III-year B.Pharmacy. The welcome address was presented by Dr N. Srinivas, Director, SNVPMV. He spoke on the significance of the conference stating that the conduct of clinical trials in India throws a lot of challenges in views of major regulatory amendments in the year 2013 and 2019, lack of clinical trial experience among medical fraternity and treatment-naïve patients. The Inaugural event was witnessed by our management members: Mr. Sainath Dayaker Shastry, Hony. Secretary (online) and Mr.B. Laxman Sena, Hony. Treasurer (offline), SNVPMV.

Dr V.Jyothi, Principal, SNVPMV in her message has encouraged the students to participate actively in all the events. Mr Laxman Sena, Hony. Treasurer, SNVPMV encouraged the students to involve actively in all the scientific sessions and co-curricular sessions organised on the occasion. Dr.T. Saritha Jyotsna, Vice Principal, SNVPMV has ended the inaugural event with a vote of thanks to all the dignitaries present.

As a part of the event, Guest speaker, **Dr Padmavati Vutukuru**, Head of the pharmacology department, Malla Reddy Medical College has delivered a talk on "Investigator perspective and challenges faced by the principal investigator (PI) in the conduct of clinical trials in India". She emphasised on responsibilities of PI and how PI can ease the challenges faced during the conduct of clinical trials in India. Speaker concluded that the success or failure of a clinical trial ultimately depends on the efficiency and capability of PI and that the role of PI is not only crucial from the conduct of study point of view but also associated with many challenges. The session was actively attended by 320 participants from 10:40 AM to 11:40 AM and the session ended with enthusiastic questions from all the participants and appreciation from Sri Sainath Dayaker Shastry, Hony. Secretary, SNVPMV about the way the talk was conducted and the zeal it created among the participants.

In the second invited talk which started at about 11:45 AM, **Mrs Suhasini Mudraganam**, MSc, MS(USA), CDE, chief nutritionist, possible(Formerly true weight) has shared her insights and thoughts on nutrition and immunity. During her exuberantly informative talk, she has stressed the importance of nutrition and immunity during this covid pandemic time and also highlighted the importance of the gut microbiome and the role it plays in immune

responses elicited by the body. The session was highly interactive with 342 participants. The session ended with questions pouring in from participants and Dr V.Jyoti, Principal, SNVPMV thanking the guest speaker and planning another session in the near future. Dr N.Srinivas, director, SNVPMV appealed to the students to develop strong skills in nutrition and immunology as most of the concerns of patients are from these areas. He informed that this session will also help in patient recruitment and retention activities if undertaken by the students in future.

The session was paused for a lunch break and followed by clinical case presentations. Some of them are given below:

Case Study 1: (5 Marks)
In a central laboratory, a pediatric sample comes in with a different name on the tube, and a different name on the paperwork. You are the technician at the central Lab & you know that asking for another blood sample from the investigator is very difficult as this is a pediatric trial. How will you proceed?
Ans: As a technician, it's your responsibility to see if this can be resolved. Over the phone? Or with fax?
Any discrepant or missing information should be communicated to the Site and verified promptly before specimens are processed, stored, or results issued. Any contact with the site personnel has to be documented in the lab data Clarification form. The protocol should mention the rejection criteria of a sample clearly.
Case study 2: (5 Marks)
You are involved in a study on a new drug for worm infestation in the pediatric population. The subjects to be included in the study are 3-18 years.

a) Describe the informed consent process.
b) What factors will determine whether one or both parents must sign the consent form?

Ans. Suggested discussion points
Written parental consent
Children aged 14-17 have the option to sign the parental consent form, if appropriate for the child and if the consent form is on the Plain Language template
Child assent (usually written, but verbal permitted) for children aged 7-14 (or 7-17)
Minimal risk: one parent
Greater than minimal risk, but the possibility of direct benefit to a child: one parent
Greater than minimal risk, and no direct benefit, but the potential for generalizable knowledge about the child's condition: both parents.

Q X Case Study 3: (5 Marks)
A sponsor wants to do a retrospective study and approaches you (investigator) to use the medical records from the patient database of your center. Can you give the past medical records to the sponsor? What steps you should take before you can hand over the past medical records?

Ans: . Investigator needs IRB permission, and the permission of the subject (taken originally) before handing over past medical records for a new study.

No patient consent required if:

i. Record review would not pose more than minimal risk to the subject.
ii. When research will not adversely affect the rights or the welfare of the subject.
When research could not practically be carried out if consent were to be taken.

Dr. TukaramBapuji Akula, CEO of Zenrise clinical, Hyderabad, enlightened students on expectations of sponsors and regulatory authorities like MHRA, WHO, USFDA on data integrity. The speaker also stressed the perspective of CRO and regulatory authorities on the conduct of clinical trials in India. In conclusion to his talk, he said data reconstruction needs to be built into a quality management system at a "policy level" and data integrity needs to become a specific focus of regular internal audit programs. The session ended with an exchange of information about volunteer inclusion criteria and awareness campaigns between Dr. Srinivas and Dr. Tukaram Bapuji. The session lasted from 3 PM to 4:30 PM.

After the extensive presentation, the Event witnessed few more case presentations till 5 PM.

About 342 students from Pharm D and B. Pharmacy courses participated very enthusiastically in the various events conducted on this day. Dr Jyothi (Principal), Dr Srinivas (Director), Dr Saritha Jyotsna (Vice Principal) and the faculty members from all the departments participated and shared their thoughts with the students. The responses from the students were overwhelming. Students are looking forward to many more webinars. There were about 408 registrations for this event and e-certificates were issued to participants following the student feedback including 10 MCQ's to evaluate their understanding of guest lectures.