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JSS College of Pharmacy, Ooty

(An ISO 901:2015 Certified Institution)

Department of Pharmacy Practice



A Brief Report on Web Lecture Series-1 held on 30.06.2020

Topic: Pharmacometrics Application in Drug Development and Patient Care

Time: 08:30 a.m. – 9.45 a.m.

Platform: Google Meet (Link: <https://meet.google.com/zpv-gjmw-etr?hs=122&authuser=0>)

Speaker: Dr Ayyappa Chaturvedulu, PhD, FCP

Associate Professor

Pharmacotherapy, System College of Pharmacy

Medical Education, TCU-UNTHSC School of Medicine

University of North Texas Health Science Centre

at Fort Worth, USA



To accomplish the notion 'Learning Never Stops at JSS', adopted by JSS Academy of Higher Education & Research, Mysuru, it was decided to organize 'Web Lectures' to our students by adjunct faculties and other renowned faculty members on specialized areas to advance the knowledge and practice. To initiate this task, the first web lecture for the academic year 2020-21 was organized by the Department of Pharmacy Practice on 30.06.2020 as per the details mentioned above.

Dr Ayyappa, an expert in the area of Pharmacometrics and its applications in drug development process delivered a lecture on the given topic. The excerpt from his lecture is given here.

The investment of money and time to bring a new drug molecule from 'bench to bedside' are increasing forever and approaching about \$ 3 Billion and 12 years respectively. Thus, it is imperative for the pharmaceutical industries to adopt various strategies towards shorten the duration of regulatory approval for the new drugs and launching safe and efficacious medicines into the market. In this aspect, the scientists and regulatory leaders at pharmaceutical industries explore the mathematical modeling and simulation tools those will minimize the risk and accelerate the process of drug development at all phases.

Pharmacometrics is the branch of quantitative clinical pharmacology that facilitates decision making throughout the drug development and regulatory approval processes. It is basically using the pharmacokinetic and or pharmacodynamic modeling and simulation. It has wide applications in the drug development process including clinical trial design and optimization of dosage regimen. This computational science has the capacity to integrate all the retrospective and prospective data from

diversified sources including but not limited to pathophysiology, system pharmacology, clinical pharmacology, statistics, etc.

It also facilitate the integration of preclinical and clinical data obtained at development phases and helps to develop a scientific framework for designing the rational dosage regimen to optimize the beneficial effect by minimizing the untoward effects of the drugs in the target patient population. There several examples as evidences to elucidate the impact of pharmacometric analysis in defining most efficacious doses, for various label claims, increased safety of the patients especially, the special population like pediatrics.

Further, it also believed and advocated that the application of pharmacometrics in drug development process will reduce the time and cost involved through valid simulations and will increase the success rate of the molecules when the INDs move from one phase to the other phase of the trials.

Apart from drug development process, the tools of pharmacometrics are also applied to optimize the dosage regimen of drugs. Few examples include dosing of antimicrobials such as Vancomycin, Gentamicin and others including antiretroviral like Tenofovir.

Couple of questions raised by the participants about, sample size calculation for pharmacometric studies, applications of simulation in pharmacometrics, appraising the statistical significance versus clinical significance was all addressed by the speaker.

Earlier, Dr S P Dhanabal, Principal welcomed the speaker and all the participants to the first web lecture of this academic year. Dr S Ponnusankar, Professor & Head, Department of Pharmacy Practice proposed the vote of thanks.

About 75 participants comprising the fifth and sixth PharmD students, faculty members and research scholars have participated in the lecture.

JSS COLLEGE OF PHARMACY, OOTY

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Web Lecture Series

Department of Pharmacy Practice

Topic: Pharmacometrics Applications in Drug Discovery and Patient Care

Speaker: Dr. Ayyappa Chaturvedulla, Associate Professor, Pharmacotherapy System College of Pharmacy, Medical Education, TCU-UNTHSC School of Medicine USA.

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Pharmacometrics Applications in Drug Development and Patient Care

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Associate Professor,
Pharmacotherapy, System College of Pharmacy,
Medical Education, TCU-UNTHSC School of Medicine
THE UNIVERSITY OF NORTH TEXAS HEALTH SCIENCE CENTER at FORT WORTH

Lecture available at: <https://youtu.be/SpNvPJzdD4>

