JSS ACADEMY OF HEIGHER EDUCATION & RESEARCH

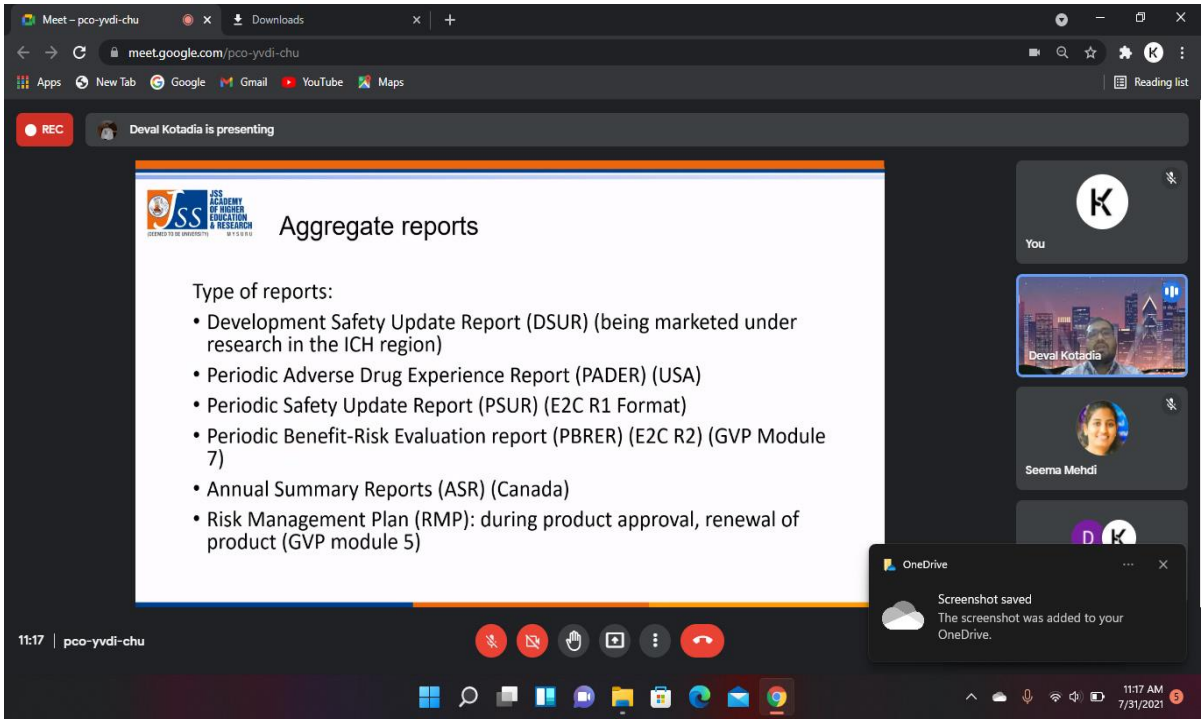
JSS COLLEGE OF PHARMACY
DEPARTMENT OF PHARMACOLOGY

REPORT OF ALUMNI SERIES ON **PHARMACOVIGILANCE: AS INDUSTRY PRACTICE (**31-07-2021)

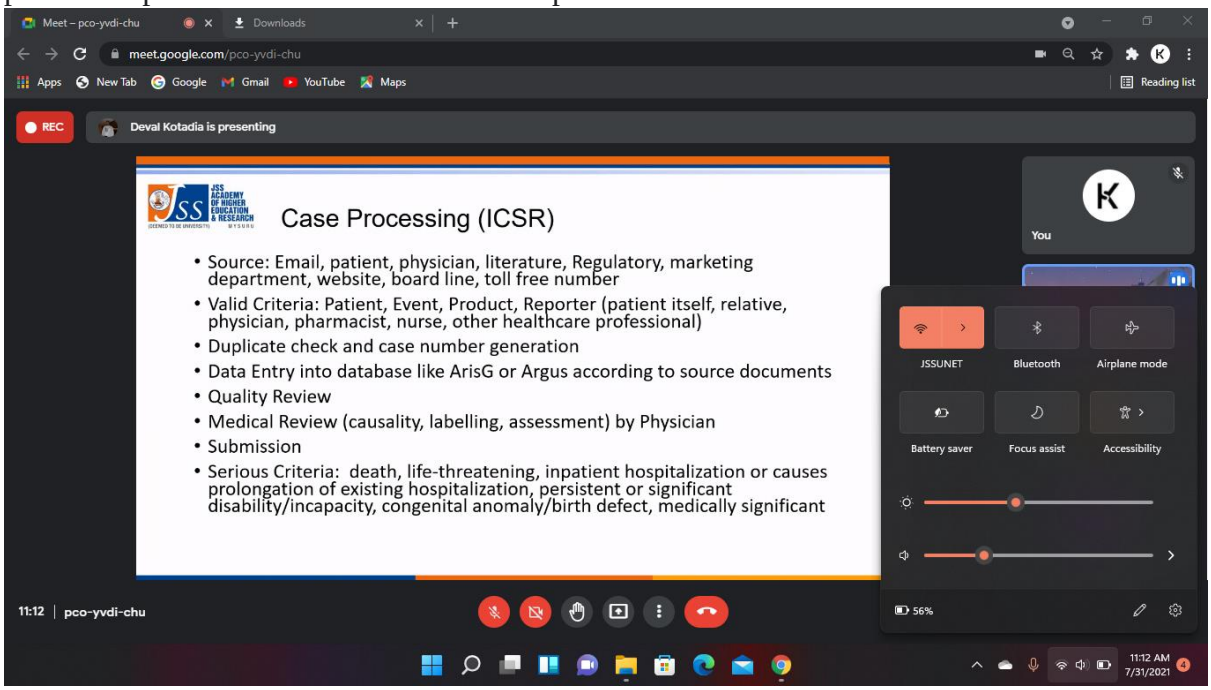
Dr. S N Manjula Professor and Head department of Pharmacology started the guest lecture by seeking the blessings of his holiness Swamiji and greeted the guest who was to deliver a lecture today to the students of M Pharm and PhD, The guest Mr. DEVAL is an Alumni of JSS college of pharmacy and completed his M Pharm in the department of Pharmacology, sir later went on and achieved laurels in the field of Pharmacovigilance. Today as Pharmacovigilance is the need of the hour and the present students require knowledge from experts in the field Mr Deval agreed even out of his busy schedule among the pandemic out of kindness agreed to deliver a talk on the Pharmacovigilance: As Industry Practice.
The objective of this lecture was to

1. Familiarise the students on the actual practices of Pharmacovigilance
2. Draw parallels from the actual practice and the theoretical understanding of Pharmacovigilance
3. Understand the global scenario of Pharmacovigilance from an expert's point of view
4. Enrich the students with knowledge of scope of pharmacovigilance and its actual practice.

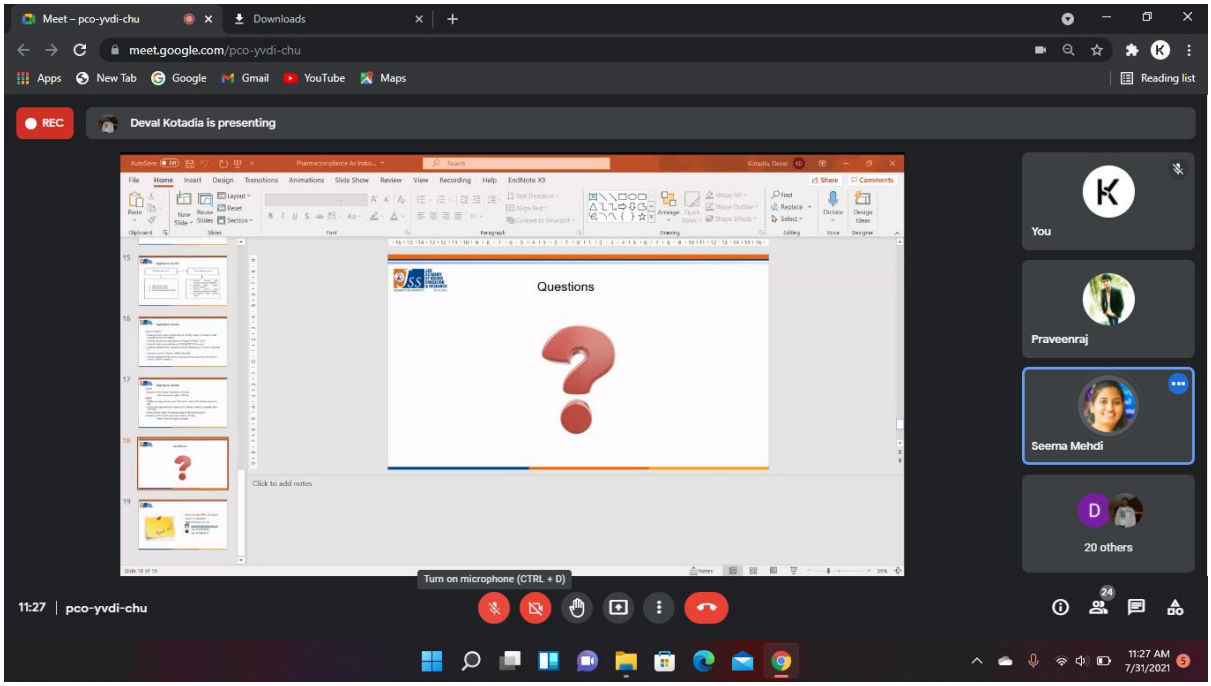
The speaker began to speak about various sub part of pharmacovigilance such that the sub branches and the topics that constitute the pharmacovigilance as a whole and taught the students about the reporting systems and types of reporting, he also spoke about development safety update report (DSUR) its use es and the importance of it as per ICH requirement, Periodic Safety Update Report (PSUR) the periodic update of the progress of either the study or the trial as per US requirement, and E2C R1 format.
The discussion later developed into the premarketing and post marketing activities and involvement of the pharmacovigilance, it was clear after this topic that the pharmacovigilance had an important role in the clinical aspect but also in the post marketing risk and benefit analysis of the released product.



The method of risk management plan during product approval and its renewal of product as per GVP module (RMP) is to document the risk management system considered necessary to identify, characterise and minimise the important risks of a medicinal product, the annual summary report (ASR) emphasised upon the overall activity of the personnel involved in the process of product related research or trial period.



The case processing topic delt with the source involved, the criteria for inclusion and exclusion of the subject the method of generation of case number and cross checking the number for uniqueness, review its quality, being reviewed by physician, **Individual Case Study Report** (ICSR) is a safety service document which includes information required for reporting the adverse events and problems related to products and complaints filed by consumers with respect to any product.



Later when the speaker had delivered talk the session was open for discussion, the enthusiastic students asked many questions which the speaker answered in detail with enthusiasm

Once the questions were answered the departmental virtual tour was organised to the guest to reflect upon the developed facility and its magnificent infrastructure.

The vote of thanks and closing statement was delivered by Ms. Seema Mehdi who was the organiser of this immensely informative session, the students were very happy and enriched with the updated and current practices of Pharmacovigilance and the students were thankful to the institution and the department of Pharmacology for taking such initiatives to develop skills and carrier.