REPORT OF GUEST/ EXTENSION LECTURE

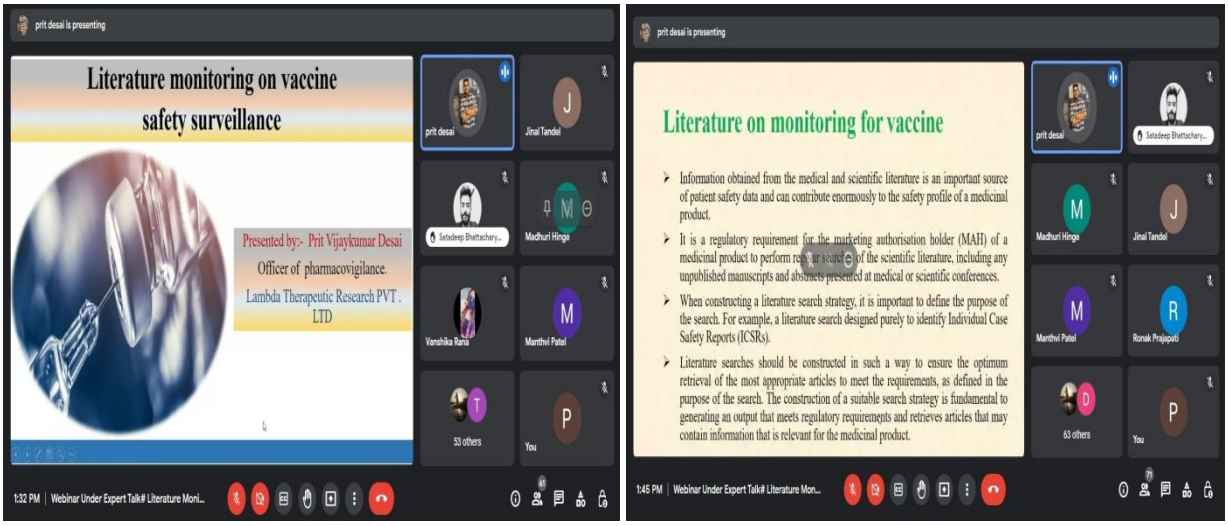
Title of Guest Lecture (Webinar): Literature Monitoring in Vaccine Safety

Speaker: Mr. Prit Desai, Officer, Pharmacovigilance, Lambda Therapeutics, Ahmedabad

Date & Venue:18th June, 2022 on virtual platform through Google meet

No of Participants: 161

Summary Report: Vaccine safety has been rigorously monitored in clinical trials, rare adverse events often go undetected as trial participants are often limited in number and followed for a relatively short duration under controlled circumstances. Mr. Desai also shared some common types of study designs in Vaccine safety surveillance. Mr. Desai also shared monitoring of vaccine safety after licensure relies upon a combination of passive and active surveillance. Passive surveillance systems, which are the foundation of pharmacovigilance, are databases into which spontaneous reports of AEFIs are collected, such as the Vaccine Adverse Event Reporting System (VAERS) in the United States and EudraVigilance in the European Union (EU). Mr. Prit also shared routine surveillance for safety signals is based upon a statistical pair-wise analysis that detects disproportionality between the number of observed reports and the number of expected reports of a single adverse event for a single vaccine. Mr Desai explained a roadmap for international collaborative epidemiological monitoring of vaccine safety in low-income and middle-income countries has been described and should be put into practice as a matter of urgency. Mr. Desai has suggested if and when a vaccine safety concern is identified, a commitment by regulatory authorities to determine how and why an AEFI, however rare, occurred is essential both to further our knowledge of the immune system and to ensure public trust in immunization programmes.



(Mr. Prit Desai delivered a session on Literature Monitoring in Vaccine Safety-2022)