Session 1: 15:55 – 16:10

Experience in vaccine clinical trials in Indonesia-an industrial perspective


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Short CV

Roestan graduated from Padjadjaran University Bandung majoring in Pharmacist, Master of Business and Administration from Bandung Institute ofTechnology, and Doctoral of Strategic Management from DIM-FEB Padjadjaran University Bandung.

He currently officiates as Operational Director of PT Bio Farma Holding, Vice Chairman OIC –Organization of Islamic Cooperation –Vaccine Manufacturer Group. He also serves as The Experts of PP Indonesian Pharmacists Association.

He began his career with Agency for the Assessment and Application of Technology Indonesia (BPPT) Jakarta and OrganonIndonesia –Akzo Nobel –a multinational pharmaceutical company based in Netherland.

He continued to grow in some strategic position at PT Bio Farma (Persero) such as President Director in 2018 –2019, Marketing Director in 2017, Corporate Secretary in 2008 –2017, Upon his careers, Roestan was one of Indonesian Delegates for World Health Assembly in 2012 –2018, WHO, Genève, Switzerland and delegates for Organisation of Islamic Cooperation –Health Minister Conference, Jeddah, Saudi Arabia.

Abstract

Communicable diseases such as pandemic of COVID-19 increasing numbers of deaths worldwide necessitate the urgent development of vaccines. Vaccine developed have been found to be safe and effective, they could induce active immunity and prevent diseases. Bio Farma develop vaccines in-house or collaborates with the partners acts as a sponsor of clinical trials in Indonesia. Trial will be conducted in accordance with the latest standard, ICH Good Clinical Practice guidelines and regulatory requirements. The investigator shall be responsible for obtaining approval of the protocol from the Institutional Ethics Committee (IEC) before start of the trial, as well as approval of all amendments in compliance with local law. Objective of the study are to evaluate the efficacy of vaccine in preventing disease evaluate the efficacy of vaccine in preventing suspected cases, evaluate the safety of the vaccine, evaluate the immunogenicity of the vaccine and evaluate lot-to-lot consistency of batches A set-up visit will be performed before the inclusion of the first volunteer in the center. The monitor and/or the responsible medic will verify and document that the material to be used during the trial has been received and that the investigational team has been properly informed about the trial, regulatory requirements and the SOPs established by Bio Farma. Clinical Research Associate will carry out regular follow-up visits. Reporting of the trial results, Bio Farma will submit the safety, immunogenicity and efficacy data for registration process to be reviewed prior for approval.