Global Vaccine and Immunization Research Forum

Contributions of Regulatory Science to Vaccine Access

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REGULATORY SCIENCE

The science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of human medical products to ensure that innovative products are available to address public health needs.

Session Objective and Targeted Outcomes

- The purpose of this session is to discuss, using two case studies, how scientific innovation can be used in regulatory evaluation and decision making with the objective of accelerating product development, and increasing the relevance of data requested for product registration in relation to the assessment of quality, safety and efficacy of vaccines.

- To develop a better understanding of how regulatory science is currently being used by regulators, to identify gaps in the application of regulatory science from a global perspective, and to identify some solutions to address these gaps.

Case Studies

Case Study I: Enhancements in laboratory research to support innovations in regulatory science for the evaluation of new vaccines

Teeranart Jivapaisarnpong, (MoPH Thailand)

Case Study II: How can innovation in regulatory science inform the regulatory process to facilitate the development of new vaccines?

Marion Gruber (US FDA)

QUESTIONS

- What are barriers to introducing regulatory science into less-resourced National Regulatory Authorities?

- What are potential solutions to barriers to introducing regulatory science into less-resourced NRAs?

- How can regulatory science enhance global access to vaccines for emerging infectious diseases?