Enhancement in Laboratory Research to Support Innovations in Regulatory Science for the Evaluation of New Vaccines

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Global Vaccine Immunization Research Forum
Hyatt Regency Bethesda
4-6 March 2014

Regulatory Sciences: Input from laboratory research (1)

Vaccine life cycle	Examples: Laboratory research
• Seed & Ag development • Pre-clinical studies • Clinical studies	• Characterization • Testing on safety, immunogenicity in vivo & in vitro • Testing subject's specimen (Ab, CMI, MI, disease diagnosis), defining correlate of immunity • Assays development

Regulatory Sciences: Input from laboratory research (2)

Vaccine life cycle	Examples: Laboratory research
• Post-licensure	• Develop more sensitive assays to detect any safety related parameters • Support product improvement

Lesson learned from R& D of Pandemic LAIV in Thailand (1)

Lab research	Constraints/Solution
• Test for seed attenuation in ferret • Toxicity studies in the pre-clinical studies	• No capacity in the country, very few labs in the world/ Use other lab assisted by WHO • No experience in study design and abnormal investigation/ Advices from regulators & experts

Lesson learned from R& D of Pandemic LAIV in Thailand (2)

Lab research	Constraints/Solution
• Measurement of immune response in clinical trial	• HAI titer was significant lower from the other country's experience/ Standardized method with experienced lab (coordinated by WHO) • No experience & assay developed for study on CMI & MI

Lesson learned from R& D of Pandemic LAIV in Thailand (3)

Lab research	Constraints
• Potency assay	• Lack of experience in method development in the concept of regulatory evaluation/ GLs, discuss with regulator

Important points of the lab research in the context of regulatory science

- The lab research should be conducted in line with the regulatory concept and procedure.
- Assays used need to be validated/ standardized .
- The research results must be reliable and should be interpreted in combination with the knowledge on vaccine characteristics and experiences in the past.

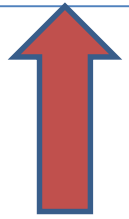
How to enhance the capacity of lab research to support regulatory science? (1)

Improve communication between regulators and research labs at the early stage on vaccine development.

Regulator's GLs

How to enhance the capacity of lab research to support regulatory science? (2)

Information sharing & research collaboration at international & regional level: Scientific Forum, Academic association, Laboratory network, Website, Publication



WHO initiation/coordination


THANK YOU