GVIRF 2018 Plenary 4: Regulatory Capacity, Challenges, and Convergences	
Rapporteur: Angela Hwang (Consultant)	
Session Outline	**Chair:** Norman W. Baylor (President and CEO, Biologics Consulting Inc.) **Presentations:** *Alternative Regulatory Pathways: Opportunities and Challenges*, Norman W. Baylor (President and CEO, Biologics Consulting Inc.) *Benefits and Challenges: How regulators can reduce time and efforts in case of public health emergencies?* Yewon Sohn (Professor, Seoul National University) *Human Clinical Trial to Support the Development of New Vaccines: Perspective from Thailand*, Akanid Wapeewuttikorn (Head of Investigational Drug, Bureau of Drug Control, Food and Drug Administration, Thailand) **Panelist:** Lucky Slamet (Independent Expert/Consultant, Badan POM)
Objectives of the session	*To discuss:* • Mechanisms to facilitate the licensure of new vaccines as well as improvements in current vaccines • Perspectives from regulatory authorities in Asia on conducting human clinical trials and evaluating vaccines in public health emergencies
Main outcome	• International collaboration and cooperation are important to build capacity for vaccine evaluation in public health emergencies.
Summary	Multiple national regulatory authorities (NRAs) have implemented alternative regulatory pathways that provide opportunities for evaluating vaccines for emerging infectious diseases. In the US, Fast Track designation, Breakthrough Therapy designation, Accelerated Approval status, Priority Review status, and the "Animal Rule" are alternative pathways provided by the Food and Drugs Administration (FDA) that allow more frequent interactions with FDA, rolling or expedited review, and in some cases the potential to achieve licensure without human efficacy trials for products meeting qualifying criteria.[a] Korea has two regulatory pathways that can be used in response to outbreaks of new infectious diseases. The Rapid Permission system allows the Minister of National Defense to import a pharmaceutical after consulting with the Minister of Food and Drug Safety (MFDS). It also allows the MFDS to permit manufacture and import of unregistered drugs to respond to infectious disease pandemics. The Fast Review process applies to products that may have therapeutic effects against life-threatening or serious diseases; products where fast introduction is deemed necessary; orphan drugs; and products for bioterror diseases or pandemic infections. It allows an applicant to submit part of the required data after placing the product on the market in order to expedite review.[b] While there is no explicit "animal rule", Korea's Regulation on Review and Authorization of Biological Products does allow exemptions to data requirements when experiments are not possible to perform. In Indonesia, expedited regulatory review is available for vaccines of public health importance. Indonesia conducts risk-based evaluations, emphasizing clear evidence of safety and efficacy. When there are gaps in scientific evidence for candidate vaccines, the

	Indonesian system considers to what extent the vaccines would bring substantial benefits to public health. For example, Indonesia approved dengue vaccine with some precautions due to its high public health importance. To foster domestic vaccine production, Thailand has defined a Roadmap for Health Innovation Development that targets domestic development and licensure of advanced vaccines over the next 15 years. The Thai FDA is supporting innovative vaccine development in Thailand, such as for a new innovative recombinant acellular pertussis vaccine developed by Mahidol University and BioNet Asia. Despite the availability of these pathways, the development of products for use against emerging infectious disease has been slow due to factors such as inadequate science, lack of commercial markets, and some cases the lack of a clear regulatory pathway to licensure. International collaboration and cooperation are important to build capacity for vaccine evaluation in public health emergencies. To accelerate progress, WHO and regulatory authorities are engaged in regulatory harmonization and convergence to align requirements and technical guidance, streamline regulatory processes, and build regulatory capacity. For example, WHO is taking the lead to aid regulators in all markets through initiatives such as the Developing Countries Vaccine Regulators Network and the African Vaccine Regulatory Forum. Regulatory training exercises and joint evaluations are also contributing to capacity building. Reliance mechanisms, whereby high-capacity NRAs provide assistance to NRAs in developing countries, are being explored, and WHO guidance is in development to advise NRAs on their implementation.
Key references or quotes	a. Guidance for Industry: Expedited Programs for Serious Conditions-Drugs and Biologics, May 2014. https://www.fda.gov/downloads/Drugs/Guidances/UCM358301.pdf b. Guide to Drug Approval System in Korea, Ministry of Food and Drug Safety, National Institute of Food and Drug Safety Evaluation, 2017. http://www.nifds.go.kr/_custom/nifds/_common/board/download.jsp?attach_no=23002