GVIRF 2016: *Preparing for the next Infectious Disease Emergency (Plenary 4)*	
Rapporteur: Joachim Hombach	
Session Outline	**Chairs**: Norman Baylor (Biologicals Consulting) and Helen Rees (University of Witwatersrand) **Presentations:** David Wood (WHO): The R&D blueprint Lucille Blumberg (South Africa national Institute for Communicable diseases): Priority diseases for vaccine development Mimi Darko (FDA Ghana): Regulatory preparedness for infectious diseases emergencies. **Discussants:** Seth Berkley (Gavi); Marco Cavaleri (EMA), Swati Gupta (Merck), Johan van Hoof (Johnson & Johnson), Speakers **Closing Remarks**:
Objectives of the session	• Present the blueprint in relation to vaccines • Present infectious diseases priorities outlined in the blueprint, and the framework for identification of R&D gaps • Discuss the regulatory research agenda of the plan with its particular relevance to the African continent
Main outcome	• The R&D blueprint constitutes an important effort to prioritize and coordinate global efforts to develop medicinal countermeasures against potential infectious diseases threats; • Regulatory preparedness is an important component in facilitating the expeditious evaluation of medicines. Legislation for public health emergency evaluation and registration of medicinal products should be established in all countries; • Besides push funding for R&D, financial incentives need to be established to insure manufacturers against financial losses if a product is developed in response to a recognized emergency where there is no sustainable market for the product once the emergency is over.
Summary (400-500 words)	The 2014-2015 Ebola epidemic in West Africa has revealed both great potential and fundamental deficiencies within existing mechanisms for rapid medical product development. Although global coordination has resulted in the clinical advancement of urgently needed novel Ebola virus vaccines along faster timelines than has ever been achieved for any previous vaccine; products arrived too late for the affected populations of the main epidemic. In response the 68 World Health Assembly welcomed the effort to develop an R&D blueprint for priority diseases against which no medicinal countermeasures exist. The development and implementation of this roadmap will be inclusive and build on multiple partner efforts. The blueprint entails five work-streams, one of which is the prioritization of pathogens. Others address the development of platform technologies, R&D roadmaps, governance & coordination as well as financing options. As to the prioritization of pathogens, WHO has released a list of five urgent diseases plus four serious diseases. Of note, Zika virus was listed in the latter category. While many criteria can be applied to disease prioritization, WHO considered in particular the risk of spill-over from animal reservoirs, human to

	human transmission, severity of the disease, evolvability and the lack of countermeasures. For example, monkeypox can be addressed by existing technology platforms against smallpox. The Ebola epidemic also revealed deficiencies in regulatory preparedness. While many countries today have clinical trial legislation in place and ICH principles apply, specific measures for public health emergencies are often lacking. These are urgently needed to give regulators a framework within which to operate and to guide on acceptable levels of flexibility in an emergency situation. Regional harmonization and collaboration, such as promoted by AVAREF, needs to be further developed. Noted were the West African efforts of harmonization following the model of EMA. Pathways for emergency use authorization and product approval exist under FDA and EMA regulations whereby prototype products could be brought to licensure. Experience from vaccine manufacturers having pursued the development of Ebola vaccines was also discussed. The previous investments into the preclinical development of Ebola vaccines helped considerably to accelerate the development path, as did the financial support to development efforts. However, what is missing at this time is a sustainable market for vaccines developed against emerging diseases threats to secure developers against financial risks. Lastly, the importance of developing sound strategies of using vaccines in all phases of the epidemic was noted.
Key references or quotes (up to 5)	A research and development blueprint for action to prevent epidemics: http://www.who.int/csr/research-and-development/en/ WHO priority diseases: http://www.who.int/csr/research-and-development/workstream1-prioritize-pathogens/en/