

GVIRF 2014 Plenary Session 7: Innovative vaccine research: the point of view of industry and biotech companies	
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Session Outline	<p>Chair: Michael Mowatt, Odile Leroy</p> <p>Opening remarks: Mike Mowatt</p> <p>Presentations: Martin Friede, Michael Watson</p> <p>Discussants: Suresh Jadhav, Michael Watson, Sanjay Singh, Kenneth Kelly, Michael Mowatt, Emmanuel Hanon, Johan van Hoof, Margaret McGlynn</p> <p>Closing Remarks: Martin Friede</p>
Objectives of the session	To identify ways to more effectively partner and collaborate between academic centres, public funders, entrepreneurs and commercial entities (venture capitalists/pharmaceutical companies) in order to maximize innovation and commercialize products.
Main outcome	<p>Public sector funding of research results in a dominant and dense patent portfolio in the public sector, resulting in diminished interest in industry, reduced innovation, and increased transactional costs. A new business model was proposed: an open access patent pool should be created for vaccines that are expected to have a low Return on Investment (ROI), at reduced costs and risks to industry, and facilitated by open access to patents without any upfront costs for the manufacturers. Early collaboration is required between industry, academy, small partners in industrialized and developing countries.</p> <p>Commercial transaction should start once the vaccine technology is ready for translation. Entrepreneurs should ensure management of IP, early partnership, and transparent benefit-sharing.</p>
Summary	<p>An analysis of funding sources and patenting activity relating to vaccines and in particular to vaccines against TB, malaria, HIV, Dengue and RSV was undertaken. This study has demonstrated that over the last two decades the number of patents on vaccines has grown exponentially, and this growth has been primarily driven by the public-sector-funded institutions. In the past know-how, rather than patents, was a barrier to industrial development and production of vaccines. As a result of this change in patenting activity, vaccine manufacturers need to negotiate a much larger number of licenses, and since there is increased technical uncertainty with regards to these new technologies, the transactional costs become inhibitory to new vaccine development. At the same time significant public funding is being invested in translational research, where early-phase vaccine development is being conducted by academic and start-up institutions which have limited experience in vaccine development and limited access to enabling technologies. This results in delays in development and sub-optimal use of resources including public funds.</p> <p>Patenting activity for all vaccines has gradually increased over the last 100 years and has experienced exponential growth over the past 30 years, with now about 10,000 patents available. Previously, patents were not considered a barrier to development. However, ownership of patents now lies primarily in public sector such as the US government, followed by GSK, and the Russian Research institute. The analysis of a subset of these patents comprising TB, HIV, Malaria, RSV, and Dengue vaccines, demonstrates that the 5 major players in industry do not own a significant proportion of these patents. This translates into manufacturers generally scoring lower on a metrics of innovation indicators compared to other stakeholders. A different model has been used by the International AIDS Vaccine Initiative (IAVI), which is a not-for-profit Product Development Partnership, and a globally integrated R&D organization that</p>

	<p>bridges government and foundation funding with academic and industry capabilities. The goal of the IAVI model is to reduce upfront risk and enable industry partner(s) to invest in late stage development, registration and launch. IAVI recognizes the importance of IP, and seeks to manage IP (data, materials, patents) to enable research in the field and facilitate industry engagement. "Access provisions" are incorporated in IAVI agreements to assure that donors' investments lead to relevant and accessible products in the world's poorest countries. The model used by this organization has met with some success but is limited in that it does not control origination or access to patents.</p> <p>A new business model is needed for vaccine development especially for diseases that have the highest burden in developing countries and where public rather than private funds are driving innovation and focusing on unmet vaccine with low industry ROI. This could include a patent-pooling system or alternatively a patent access system such as the WIPO Re-Search project, but should also include earlier partnerships in development bringing together the academic sector, translational research groups and also vaccine manufacturers from industrialized and developing-countries.</p>
<p>Key references or quotes</p>	<ul style="list-style-type: none"> • Johan van Hof "There is a need for very early partnerships starting with the development of murine and other animal models and a focus on fit-for purpose, efficiency, as well as matching of CMC with development skills." • Johan van Hof "De-risking is very important, and can be addressed by collaborating in the pre-competitive space, designing appropriate predictive toxicology and animal studies, making use of human challenge trials." • M. McGlynn In general, there are two cases of vaccines: 1. HIV – for these vaccines we need to see a profitable development cycle (ROI), a developed world market, as well as access commitment; 2. For the second group of vaccines, ROI is not relevant because these vaccines only target developing world markets. The development of these vaccines can only be enabled by non-profit funders/resources, industry participates for social good." • M. Friede "We need new support mechanisms for vaccines against poverty diseases". • M. Mowatt "Universities may not be willing to contribute patents to pools."