J Vaccines Vaccin 2017, 8:3(Suppl)
DOI: 10.4172/2157-7560-C1-058

Human vaccines project: Decoding the human immune system to accelerate next generation vaccine development

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Vaccines have been one of the most effective public health interventions over the last century, preventing and controlling a broad spectrum of infectious diseases. However, over the last 15 years there have been several failures in late stage vaccine and immunotherapeutic development programs, against viral, bacterial, parasitic and neoplastic diseases. These failures are due to the lack of understanding of the human immune system and reliance on empiric strategies for vaccine development that are unlikely to be effective in the future. The Human Vaccines Project (Project) is a nonprofit public-private partnership that has been established to accelerate development of next generation vaccines and immunotherapies for major global infectious and neoplastic diseases by decoding the human immune system. The project has created a unique model of engaging multinational pharmaceutical partners with key stakeholders from academia, governments and non-governmental organizations, into a human immunology-based, milestone driven, global research consortium. The project aims to decode the human immune system by establishing and following a series of decade long cohorts, varying by age, gender, ethnicity and geography, for deciphering the human "immunome". This will include the repertoire of B and T cell receptors of the human immune system, and the immune targets recognized by antibodies and T cells for selected infectious and neoplastic diseases to facilitate vaccine discovery. The project also aims to elucidate the "rules of protective immunity" in humans by conducting strategic, small, iterative exploratory clinical research trials of licensed and experimental vaccines and immunotherapies to systematically solve the key problems impeding next-generation product development. Proposed pilot studies of the project aimed at assessing the human immunome and immune responses to vaccines across heterogeneous populations will be discussed.

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Virus safety for viral vaccines and vectors

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Viral vaccines and viral vectors processes present special challenges for virus safety. Viral clearance approaches traditionally used in biopharmaceutical products, such as size exclusion or chemical inactivation, are often not useful when the product itself is a virus or a living cell. Considering lessons learned from the past, regulatory bodies and industry have striven to understand the risk associated with manufacturing of vaccines and novel therapies and to implement barriers to potential viral contaminants. This presentation will examine application of virus safety principles to virus-based products. Selection of virus-free raw materials, safety testing of cell and virus stocks and sensitive tests for detection of contaminating viruses during the manufacturing process are critical elements of a viral safety plan. Viral clearance steps may also be useful in some circumstances, such as the removal of helper viruses from viral vectors. These approaches can be combined to create comprehensive viral safety strategies that minimize the risk of viral contamination.

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