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In pursuit of the unknown: Standardizing endpoint assays for evaluating complex immunological signatures

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Bacille Calmette-Guérin (BCG) remains the only licensed vaccine for tuberculosis (TB). While BCG has been shown to be effective in preventing certain forms of childhood TB, adult pulmonary TB continues to be a serious burden, with 8.6 million new cases and 1.3 million deaths reported in 2012. Despite the availability of drug therapies, TB remains one of the leading causes of death by an infectious disease worldwide. Furthermore, the emergence of drug-resistant strains of *Mycobacterium tuberculosis* (Mtb) emphasizes the need for a new and effective vaccine. However, TB vaccine development has been hindered by suboptimal and expensive animal challenge models in the face of limited funding, the lack of a human challenge model, and a lack of a correlate of immunity or protection. In addition, immune assays used in evaluating vaccine candidates are variable, particularly assays measuring cellular responses. Here we discuss some of the issues with cellular assays and show the results of the qualification of a 13-color intracellular cytokine staining (ICS) assay that includes the detection of phenotypic markers, memory markers, and 7 T-cell functions (IFN-γ, IL-2, TNF, IL-17, IL-22, CD107a, and CD154). We show that at least partial qualification of this complex assay is feasible and propose a useful method for assessing assay variability and performance over time for cellular assays used in clinical trials.

Biography

David A Hokey is the Sr. Director of Immunology & Animal Studies at Aeras, a nonprofit biotech advancing the development of new tuberculosis vaccines. He received his PhD in Immunology from the University of Pittsburgh in 2005 where he worked on dendritic cell-based tumor vaccines. He then performed his Postdoctoral research with Dr. David Weiner at the University of Pennsylvania, focusing on DNA vaccines for HIV, cancer, and influenza with an emphasis on primate immunology and polychromatic flow cytometry. His current work at Aeras involves evaluation of immune responses to TB vaccine candidates in pre-clinical and clinical settings.His research interests include evaluation of novel vaccine platforms and adjuvants for manipulation of immune responses.

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