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## The human viral challenge model-accelerating vaccine development

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Since the beginning of the millennium, Human Viral Challenge Studies have successfully been conducted at hVIVO to develop a series of well-characterised virus stocks, whilst demonstrating that the Human Viral Challenge Model (HVCModel) could be effective in offering a faster and cost-effective route to market for their therapeutics. The Human Viral Challenge Model enables global pharmaceutical and biotechnology companies, as well as leading academic groups and government institutions, to undertake scientific research, accelerate the drug development timeline and reduce the cost of bringing vaccines, antiviral drugs and diagnostics to market. The HVCModel also enables fundamental research into the human response to infection and crucial research into modes of infection and transmission between individuals in the community. The HVCModel has become widely accepted as an alternative to traditional early stage field trials to show the efficacy of vaccine and antiviral therapeutics in Influenza, Respiratory Syncytial Virus (RSV) and Human Rhinovirus (HRV). By monitoring the entire disease lifecycle as subjects move from healthy to sick and recover back to healthy again, we can obtain high quality, longitudinal data from the before, during and after phases of disease. The model can be used to study the efficacy of new therapies and also to study the target disease itself. Such studies provide key outcomes about promising investigational medicinal products, their mechanism of action, and their most appropriate dose and dosage regimen, which can then be applied to design further Phase IIb and Phase III studies.

### Recent Publications

1. Wilkinson, Tom M (2012) Preexisting influenza-specific CD4+ T cells correlate with disease protection against influenza challenge in human. *Nature Medicine* 18:274–280.
2. DeVincenzo, John P. (2014) Oral GS-5806 Activity in a Respiratory Syncytial Virus Challenge Study. *N Engl J Med* 371:711-722.
3. DeVincenzo, John P. (2015) Activity of Oral ALS-008176 in a Respiratory Syncytial Virus Challenge Study. *N Engl J Med* 373:2048-2058.
4. Lambkin-Williams, Rob (2016) An Intranasal Proteosome-Adjuvanted Trivalent Influenza Vaccine Is Safe, Immunogenic & Efficacious in the Human Viral Influenza Challenge Model. Serum IgG & Mucosal IgA Are Important Correlates of Protection against Illness Associated with Infection. *Pone* 11(12):e016308.
5. Lambkin-Williams, Rob (2018) The human viral challenge model: accelerating the evaluation of respiratory antivirals, vaccines and novel diagnostics. *Respir Res.* 1:123.

### Biography

Anthony S Gilbert has obtained his Bachelor of Medicine and Bachelor of Surgery degree from the University of the Witwatersrand, South Africa. He is a Member of the Institute of Clinical Research. He has served as an expert Member and Vice Chair of a National Research Ethics Service (NRES) committee, having been appointed by the Health Research Authority in the U.K. As a Principal Investigator, he has supervised and conducted viral challenge studies in order to further the quest to bring safer and more effective vaccines and antivirals to the global community. His research has been published in several medical and scientific journals, including *Nature Medicine*.

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