

SGS Abstract for the Immunovalley conference, 31st May, Utrecht, The Netherlands

In virus inoculation studies, healthy volunteers are inoculated with established challenge strains of a virus. If besides the inoculation with the virus, the volunteers are administered an investigational drug (antiviral, vaccine, immunomodulatory...), the studies are called viral challenge studies. Challenge strains are attenuated viruses that produce a much milder set of symptoms compared to naturally occurring virus.

In current clinical research practice, viral challenge studies are used as proof of concept (POC) trials. Healthy volunteers are inoculated with a challenge strain of a virus, usually influenza and administered a vaccine or antiviral before or after the inoculation (see below).

Conducting viral challenge studies in a controlled quarantine environment allows for a superior study design; this is more cost-effective and critically accelerates the selection of a safe and effective dose, and dosing regimen, for a new antiviral drug or vaccine, as it allows for an early detection of efficacy. It therefore lowers the risk of performing a large field based phase III study. Due to their nature viral challenge studies can only be performed in specialized Clinical Pharmacology Units (CPU)

SGS Life Science services has a unique service offering in this field, combining both its scientific, medical and regulatory expertise in the field of infectious diseases, as a state-of-the-art quarantine unit where challenge studies can be performed.