hVIVO
part of Open Orphan plc

Infectious Diseases

Influenza vaccines and treatments

Seasonal influenza ("flu") causes significant morbidity and mortality each year and a pandemic influenza continues to pose a worldwide threat. Government health agencies and organisations and a large number of academic, public and private organisations, encourage development of universal / broad spectrum flu vaccines. Novel correlates of protection are being explored and the role of cellular immunity has come to the forefront of vaccine research. Healthy volunteer human challenge models of wild-type influenza will play a major role in this development process.

PROVEN FLU DISEASE MODELS

hVIVO has been studying influenza for over 20 years and been conducting influenza human studies with over flu disease models for more than 15 years.

We have conducted numerous flu challenge studies for a range of industry, governmental and academic clients, making our models the most well-used commercial flu disease models available on the market

Flu Vaccines

Conceptual Challenges

Demonstrating efficacy of novel vaccines in the field is time-consuming, costly and associated with risk

- Initial exposure to virus unknown
- Variation in circulating strains
- Large study size and duration
- Difficult to power for clinical efficacy
- Seasonality limitations
- Biomarker identification difficult

hVIVO Human Challenge Models:

Towards a deeper understanding

- Effective exploration of vaccine efficacy & correlates of protection
- Match study design to product mechanism of action
- Immunological Assays
- Host Response Analysis

Primary & Secondary Endpoints:

- Time to parasitaemia
- Reduction in incidence of symptomatic infection
- Reduction in disease severity

Antiviral/Treatments

Conceptual Challenges

Establishing efficacy of antivirals in early clinical trials is challenging Initial exposure to virus unknown

- Initial exposure to virus unknown
- Dose ranging and timing difficult
- Comorbidities and other confounders

hVIVO Human Challenge Models:

Towards a deeper understanding

- Study design matched to investigational product mechanism of actions
- Optimisation of treatment timing
- Time-dependent measurements of biomarkers
- Triggered-dosing options (time or virological)
- Controlled strain exposure
- Consistent placebo response
- Efficient resistance monitoring

Immunomodulator

Conceptual Challenges

Demonstrating clinical efficacy in early stage field trials is challenging Initial exposure to virus unknown

- Baseline prior to infection unachievable, difficult to establish host response
- Effect with/without standard of care treatment difficult to establish
- Large study size and duration
- Circulating strain variation
- Biomarker identification difficult

hVIVO Human Challenge Models:

Towards a deeper understanding

- Well controlled quarantine environments
- Baseline well established prior to infection
- Appropriate for both prophylaxis and treatment
- Flexible dosing and timing
- Establish safety & efficacy to impact infected subjects host response
- Investigate and demonstrate target engagement
- Controlled combination-treatment with drug and standard of care or antivirals