The hVIVO hMPV Challenge Model

Developing the world's first commercially available hMPV challenge model

The pilot study has proven successful development of the model, establishing a safe and reproducible disease. The study is now being extended to provide additional data to ensure accurate sample size calculations for subsequent vaccine efficacy testing.

The Model Outline?

Our healthy participant screening involved assessing the subject's health status and suitability, along with collecting serum and PBMC samples to analyse the impact of pre-existing immunity on infection. The challenge agent was inoculated using pipette droplets administered into each nostril. Following inoculation, disease monitoring assessments included two daily nasopharyngeal swabs (NPS) for virus quantitation via RT-qPCR and the completion of a symptom diary card three times daily (among a larger set of endpoints).

Screening Phase	Inpatient Phase: Quarantine/Isolation and Challenge Agent Innoculation			Outpatient Phase	
Day -90 to Day -2/-1	Day -2/-1	Day 0	Days 1 to 11	Day 12	Day 28 (+/- 3 days)
Screening	Quarantine admission Study-specific consent Initial assessments	Challenge agent inoculation Assessment as per Schedule of Events	Assessments as per Schedule of Events	Assessments as per Schedule of Events Discharge from quarantine unit	Final follow-up visit

Disease characteristics

Eight subjects were inoculated with hVIVO's A2 GMP challenge strain, with no safety concerns observed. All procedures were well tolerated throughout the study.

Self-reported symptoms were in line with expectation. Peak hMPV symptoms occurred between days 3 and 5 and we noted a faster onset and rise to peak compared to the well-established RSV challenge model.

The infection rate was 100% (8/8), with all subjects having at least two detectable PCR results within 48 hours post-inoculation. Additionally, 87.5% (7/8) of subjects had quantifiable PCR results over the same period, confirming a high level of viral replication.

Symptomatic infection was observed in 63% (5/8) of participants, all of whom reported experiencing cold-like symptoms. Furthermore, 50% (4/8) developed Grade 2 symptoms, indicating a moderate level of illness. These findings provide valuable insight into the challenge model's ability to establish infection and symptomatic disease.

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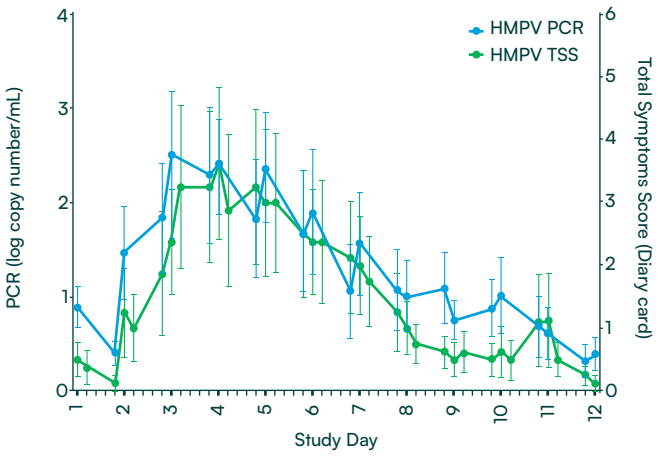
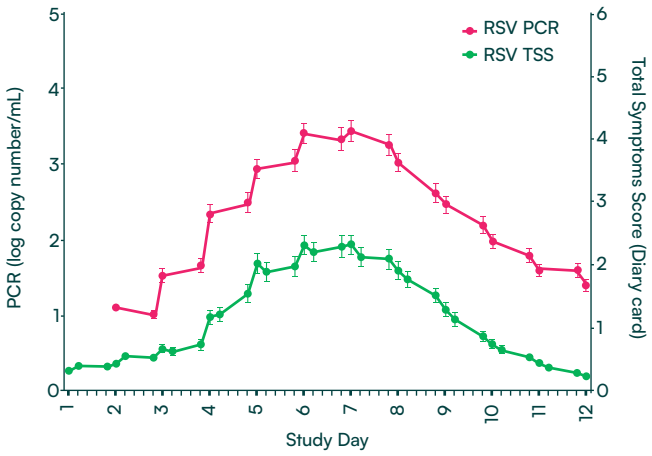
hMPV versus RSV challenge model



hMPV, n=8 (100% infected)



RSV example study, n=370 (72% infected)

The hMPV pilot study demonstrated a robust correlation between PCR results and symptom profiles among subjects, indicating consistency in infection and disease progression. Subjects exhibited slightly higher mean peak symptom scores compared to those typically observed in the well-established and highly successful RSV challenge model.

Peak hMPV symptoms occurred between days 3 and 5, with a faster onset and rise to peak compared to RSV, although the total symptom duration was similar. This alignment in disease course, combined with the favourable comparison to the RSV model, provides a high level of confidence in the hMPV challenge model's reliability and utility for future vaccine testing and antiviral development.

Why use a Human Challenge Study to accelerate your drug development?

Scientific
- Generates invaluable dosing, safety and efficacy data
- Helps optimise for larger field trials
- De-risks Phase III programs
- Controlled viral strain

Clinical Development
- Requires fewer subjects
- Significant time savings
- No seasonal requirement
- Efficacy readout not thwarted by low viral subtype circulation

Financial
- Significant valuation uplift for Biotech sponsor
- Quick, cost-effective data in a tight funding environment
- Allows products to "Succeed fast" or "Fail Fast"

Regulatory
- Potential for Fast Track or Breakthrough designation - accelerating time to market
- Potential approval and Emergency Use Authorisation

Contact us to find out more

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