How we Supported a Global RSV Clinical Development Programme

CASE STUDY

Background

An EU-based biotechnology company launched a Global Respiratory Syncytial Virus (RSV) Programme to develop and validate new approaches for managing RSV infections. The company planned to assess the viral load in nasal swabs using advanced diagnostic techniques. To achieve this, they initiated five multi-centre field trials across 82 sites, involving 244 patients over 53 months.

Objective

The primary goal was to determine the viral load taken from nasal swabs using plaque assay and qPCR in 5 IMP studies. In addition, for the non-IMP studies the focus was on evaluating the efficacy of RSV Stabilisation Transport Matrix for the long-term stabilisation of RSV Viral RNA, as well as the batch generation, characterisation, and stability testing of an RSV B strain (Strain 18537).

Our Solution

hLAB's specialised virology laboratory played a critical role in supporting the programme by providing extensive virology and analytical expertise.

1. Provision of Kits and Swabs

We supplied 1,460 kits for the trials, ensuring that each site had the necessary materials for sample collection and processing.

2. Sample Processing and Analysis

The laboratory processed 1,830 swabs, performing 1,786 plaque assays and 1,784 PCR assays. These analyses were crucial in accurately determining the viral load and assessing the effectiveness of the RSV Stabilisation Transport Medium.

3. Advanced Viral Panel Testing

Our hLAB team utilised the BioFire Respiratory Virus Panel, conducting 170 tests that further characterised the RSV strains present in the samples. This advanced panel provided comprehensive data on viral presence and load, enhancing the robustness of the study findings.

4. Stability and Efficacy Evaluations

The laboratory supported the evaluation of the long-term stabilisation efficacy of RSV Viral RNA, which was critical for ensuring reliable results across the extended duration of the trials. Additionally, batch generation, characterisation, and stability testing of the RSV B strain 18537 stock were performed, ensuring consistency and reliability of the viral materials used in the study.

Impact

Our specialised virology laboratory enabled the biotech company to conduct rigorous and reliable assessments of RSV viral loads across multiple sites and trials. hLAB's high throughput and precise diagnostic capabilities were instrumental in developing and validating the effectiveness of the RSV Stabilisation Transport Medium and contributed significantly to the overall success of the clinical development programme.

This partnership highlights the importance of specialised laboratory support in complex, multi-centre clinical trials, particularly in the field of virology, where precise and reliable data are crucial for the development of effective therapeutic and diagnostic solutions.

40 Bank Street, Canary Wharf, London, E14 5NR

@hlaboratory www.hlabservices.com