Case Study

Influenza Treatment Clinical Trial

Type of study

A Randomized, Double-Blind, Placebo Controlled Trial to Evaluate the Efficacy and Safety of a New Therapy in the Treatment of Uncomplicated Influenza.

Phase: 3

Key Achievements

- Full global study - providing full transparent results in 1 single database
- Special preparation and aliquoting for the sample handling of nucleotide sequencing
- Successful collaboration with clients on customized plan to ramp up testing according to the needs and resources
- Entire team met strict deadlines to provide results and accurate information in the database

Study Details

Patients Screened: ~1300

Patients Enrolled: ~ 1200

Sites: ~ 35

Regions-Countries: North America and Asia Pacific (including Australia)

Services Provided:

- Safety testing: hematology, biochemistry, lipid panel and urinalysis
- Culture to detect influenza A & B (MDCK/ Rhesus)
- RT-PCR using ePlex© Respiratory Pathogen Panel
- Viral load by quantitative culture ($TCID_{50}$)
- Sample handling: nucleotide sequencing (HA & NA), blood sample for PK, and blood sample for anti-influenza antibodies

Timeline

Challenges

Testing algorithms were complex as multiple PCR results had to be obtained from each sample, with only a single freeze-thaw cycle. Shipping the virology samples was also a challenge since maximum effort should be made to ship samples on the day, alternatively they would be stored and shipped refrigerated within 48 hours, or on dry ice later.

Successes

We met all kit-building and shipping timelines, despite complex coordination and rapid ramp up of testing volume. The client was able to track the status of testing in real time, using the Cerba Trova tool. Results were delivered on-time, prior to the database lock.

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