Case Study

Tuberculosis Clinical Trial

Type of study

An Open-Label, Partially Randomized Trial to Evaluate the Efficacy, Safety and Tolerability of a 4-month Combined Treatment Compared to a 6-month Control Treatment in Adult Participants with Drug-Sensitive Smear-Positive Pulmonary Tuberculosis (DS TB) and a 6-month Treatment in Adult Participants with Drug Resistant, Smear-Positive Pulmonary Tuberculosis (DR-TB)

Phase: IIc

Key Achievements

- Full global study - providing full transparent results in 1 single database
- Implementation of multiple protocol amendments
- Optimization processes to ensure efficiency and a streamlined workflow

Study Details

Patients Screened: ~750

Patients Enrolled: ~ 450

Sites: ~ 30

Regions-Countries: Latin America, Europe, Asia Pacific and South Africa

Services Provided:

- Safety testing, including hematology, biochemistry, urinalysis (dipstick, sediment and biochemistry), serum pregnancy, coagulation, and urine drug screening
- Serology testing
- HIV status
- Male reproductive hormone tests (MRHT)
- Flow cytometry
- Sample handling: blood samples for PK

Timeline

Jul '18 — FPFV

Mar '20 — LPFV & LPLV

Challenges

Many sites lacked materials to perform monovenopuncture collection. In addition, high patient screening and enrolment rates made it hard for sites to manage kit supplies. Lastly, while all clinical reports were shared with the investigator, no system existed that alerted investigators of alert values.

Successes

Extra materials and instructions were provided to those sites that lacked monovenopuncture capability. A plan to track and manage kit supplies was implemented. A system was programmed to automatically alert Investigator of reports containing alert values.

Cerba Research

CERBA RESEARCH HQ
Industriepark Zwijnaarde 3
9052 Gent, Belgium

Tel: +32 9 329 23 29
info@cerbaresearch.com
www.cerbaresearch.com