Case Study

Drug-Resistant TB Clinical Trial

Type of study

A Partially-Blinded, Randomized Trial Assessing The Safety And Efficacy Of Various Doses And Treatment Durations Of Combination Therapies In Participants With Pulmonary Infection Of Either Extensively Drug-Resistant Tuberculosis (XDR-TB), Pre-XDR-TB Or Treatment Intolerant Or Non-Responsive Multi-Drug Resistant Tuberculosis (MDR-TB)

Phase: 3

Key Achievements

- Full global study - providing full transparent results in 1 single database
- Ensured continuity of the client's screening and randomization targets
- Optimization processes to ensure efficiency and streamlined workflow

Study Details

Patients Screened: ~275

Patients Enrolled: ~ 175

Sites: ~ 10

Regions-Countries: Europe & South Africa

Services Provided:

- Safety testing including hematology, biochemistry, urinalysis (dipstick, sediment & biochemistry), coagulation and urine drug screening
- Serology testing
- HIV status
- Viral load flow cytometry
- Sample handling: blood samples for PK

Timeline

Challenges

Due to high patient screening and enrolment, some African sites were unable to manage kit supplies. Moreover, shipments proved challenging towards year-end and, especially, during the outbreak of the Covid-19 pandemic. The outbreak also caused strong restrictions on (international) shipping.

Successes

We successfully implemented a plan to track and manage kit supplies with the CRO and Sponsor. A proactive resupply process was implemented as well. An extra permit was solicited to ensure continuity of shipments and patient visits. A rapid change or couriers allowed us to secure connections and short TAT during the Covid-19 pandemic outbreak.

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