eurofins | Bioanalytical Services

Biologics Done Right

Case Study

Delivering Flexibility in a Multi-site Global Harmonized Clinical Trial

Number of US Clinical Sites: 12

Patient Population:
Patients suffering from a life-threatening inflammatory syndrome

Therapeutic Area: Autoimmune

Drug: Human monoclonal antibody

Molecular Target: Inflammatory cytokine

Study Phase: Phase II and III

Bioanalytical services:
PK and 3 PD Biomarkers with 24 hour notice prior to the shipment of samples with rapid turn-around time

Data Delivery: CDISC format

PROJECT AT A GLANCE

The project required Eurofins Bioanalytical Services to perform cross validation of a Pharmacokinetic (PK) assay and three Pharmacodynamic (PD) biomarker assays. This required supporting sample analysis for sites in the United States within a global clinical trial. The samples analyzed are from pediatric patients with a rare, complex and life-threatening inflammatory syndrome. The client's drug (where there is currently no treatment) is a monoclonal antibody biotherapeutic designed to bind and neutralize an inflammatory cytokine, which drives the pathogenesis of the disease.

PK and PD biomarker data are required in near real-time to understand the disease evolution during treatment.

SITUATION

A major Eurofins Bioanalytical Services client awarded the program based on our core assay development expertise as well as our ability to turn around clinical samples within a 24 hour period. The program depended on a closely monitored plan requiring:

- Four analysts and one supervisor working a second shift
- Establishing a communication matrix
- Data transfer agreement in FDA CDISC format
- Sample analysis and Quality agreements

Sample Analysis at the

RIGHT TIME & RIGHT PLACE

to satisfy data delivery requirements

CHALLENGES

The patient population have a rare, complex, and life-threatening inflammatory syndrome that required immediate PK and PD data to understand the disease evolution during treatment, thus dependent on our ability to turn around analyses. Our project team needed to be available on-call 24/7 with only a 24 hour notice that samples would be delivered to our lab. In order to achieve maximum productivity and for dose escalation purposes, a well-organized communication matrix needed to be in place to receive, analyze, QC, and report results back to the client's clinical team the following day.

SOLUTIONS

Together with the client, we collaborated on a plan of action including:

- Utilizing multiple analysts in validation and in assay training, which resulted in having a 'pool' of trained analysts to respond quickly when samples arrived
- Incorporating a communication matrix to establish a decision tree process for unanticipated lab results, minimizing delays
- On-call qualified staff around the clock
- Mitigating risks via weekly client meetings

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About Eurofins Bioanalytical Services

Over 20 years of industry-leading global **Scientific Expertise** supporting the widest breadth of Biologics' clinical trials with PK/TK, ADA, NAb and Biomarker assays and sample analyses.

Versatile Performance and Project Management Excellence to adapt to a client's specific needs. Clinical or preclinical, regulated or non-regulated, assay development, qualification or validation; we custom design our support to match the client's program.

State-of-the art laboratory facilities in St. Charles, MO, USA providing **Global Reach and Capacity** to address clients' needs while simultaneously offering regionally-based solutions.

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