Case Study

Multiple Myeloma Clinical Trial

Type of study

A Multicenter, Randomized, Open-Label Study to Compare the Efficacy and Safety of 2 Different Combination Therapies in Subjects with Refractory or Relapsed and Refractory Multiple Myeloma.

Phase: 3

Key Achievements

- Full global study - providing full transparent results in 1 single database
- Successful implementation new assay: used for several follow-up trials
- Successful assay transfer to USA
- Scientists: Musafa Hossein and Sabine Defasque

Study Details

Patients Screened: ~575

Patients Enrolled: ~ 450

Sites: ~ 90

Regions-Countries: North America, Eastern Europe, Western Europe and Asia Pacific (including Australia)

Services Provided:

- Thyroid function tests
- Routine testing (incl. hematology, biochemistry, urinalysis)
- Beta-2-microglobulin (serum)
- Serum and urine electrophoresis
- Serum and urine immunofixation
- Serum free light chains (SFLCs): kappa and lambda
- Total immunoglobulins: IgM, IgA, IgG, IgD & IgE
- Viral load: Epstein-Barr virus
- Sample handling: samples for biomarker analysis in saliva, biopsy blocks/slides, BMA smears, whole blood samples and PK samples

Timeline

Challenges

The quality and volume of bone marrow samples, and the streamlining of the testing flow for downstream applications on isolated cells with limited volume formed challenges for in-house scientists and sponsor.

Successes

Clear communication with the sites on sampling technique allowed for the maximization of bone marrow draws. The assay was successfully transferred to other sites (USA), and the reporting for protein electrophoresis was standardized.

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