Case Study
Hemato-oncology
Multiple Myeloma

Type of study

A Randomised, Open-label, Multicentre Phase 3 study to compare progression-free survival upon 2 different combination therapies (with a targeted MoA) in patients with Relapsed or Refractory Multiple Myeloma.

Phase: 3

Key Achievements

- Full global study - providing full transparent results in 1 single database
- 100% timelines were met by study teams
- Study period of 6 years, analyzed ~275.000 samples
- All genomics work consolidated by Cerba Research
- FDA-approved therapy for multiple myeloma
- Results published in peer-reviewed journal, The Lancet Oncology

Study Details

Patients Screened: ~1.300

Patients Enrolled: ~ 1.100

Patients Completed: ~ 1.060

Sites: ~ 295

Regions-Countries: North America, South America, Eastern Europe, Western Europe, Asia Pacific (incl. Australia and Japan)

Services Provided:

- CD138+ cell isolation
- FISH analysis on Bone Marrow Aspirate
- Total Immunoglobulins: IgG, IgA, IgM, IgD, IgE
- CD3+ T-cell isolation
- Cell Clonality by Flow Cytometry
- SPEP/UPEP for Monoclonal gammopathy of undetermined significance (MGUS or M-Protein)
- Immunofixation: serum and urine
- Serum free light chains (sFLCs)

Timeline

Challenges

Sponsor had aggressive study timelines; frequent changes to the protocol; CD138+, FISH and cell clonality added after study start; Japan added as a separate study later as well. Sponsor monitored TAT closely and wanted centralized genomics testing and aggregate reporting.

Successes

Study teams consistently met timelines; Sponsor consolidated all genomics work for the program with Cerba Research/Cerba. Custom BM and SPEP/UPEP TAT reports and comprehensive Genomics Report were created to meet Sponsor's needs

Cerba Research

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