Case Study

The Value of Multiple Myeloma Imaging Expertise:

Getting it right while meeting trial timelines to support accelerated FDA approval

Background

The landscape of new therapies in multiple myeloma trials is rapidly evolving, with stringent regulations around blinded independent central review (BICR) for efficacy endpoints and the need to integrate multiple clinical parameters to determine disease response, per the International Myeloma Working Group (IMWG) consensus criteria (2016).

As a result, it's imperative that sponsor of multiple myeloma clinical trials partner with an imaging core lab they can rely on, as evidenced in the example presented here.

Overview

A leading biotechnology company partnered with Perceptive Imaging for hematology imaging services in support of a phase II trial investigating a compound for a novel multiple myeloma treatment. Patient enrollment had begun, and images from several patients' baseline visits had already been collected.

Because the data from the multiple myeloma imaging reads would support the study's primary efficacy endpoint, it was critical that the imaging processes were compliant with global regulations.

However, this study presented numerous challenges that needed to be addressed.

Challenge 1: Inconsistent Modalities

Upon initiating reviews of the collected images, Perceptive's imaging scientists identified inconsistencies in the modalities being used across the sponsor's 30+ investigative sites. Fully understanding the current regulations and the need for consistency, Perceptive provided guidance on which modalities should be used, per IMWG 2016 consensus criteria and based on the specific indication the sponsor was pursuing.

After numerous discussions over an extended time, the sponsor and their CRO partners agreed with Perceptive's advice and updated the protocol to ensure image acquisition consistency.

Perceptive got to work developing Imaging Acquisition Guidelines which outlined the required modalities and investigative site processes. While this step added time to the process, it was critical in ensuring the sponsor captured the most valid imaging data in compliance with regulations.

Leveraging Perceptive's scalable service model, additional project managers and scientists were assigned to meet study timelines.

Although the study didn't start out on an expedited timeline, because of the time needed to put the right imaging processes in place, Perceptive quickly went into accelerated mode. Leveraging our scalable service model, the Perceptive team added project managers and scientists to the project team to ensure the sponsor's timelines wouldn't be impacted by the changes that were necessary to properly collect and process the study's critical imaging data.

Challenge 2: Manual Lab Data

In addition to using imaging to evaluate plasmacytoma changes, multiple myeloma trials require the evaluation of multiple lab parameters, including serum M-protein, urine M-Protein, serum free light chain, and bone marrow plasma cells (IMWG 2016) to determine treatment response (Figure 1).

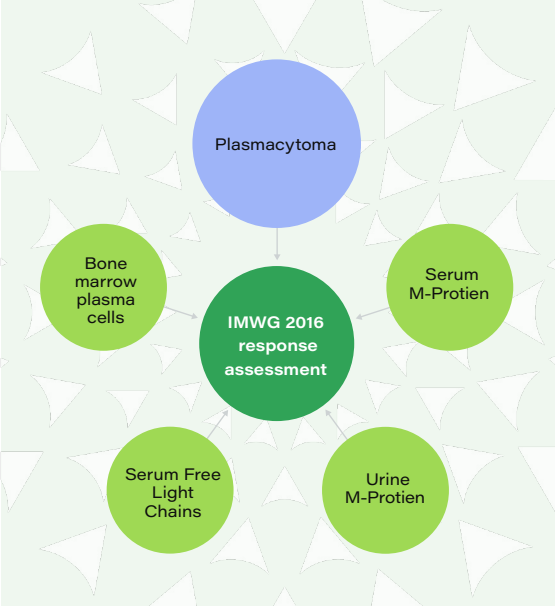

Figure 1: Clinical parameters and imaging results are integrated to determine response in Multiple Myeloma per the IMWG 2016 criteria

This added an extra layer of complexity to the trial, as those lab values were presented in PDFs, which required manual review by Perceptive's scientific/medical team in conjunction with the reviewer's image assessments which were captured in Perceptive's platform.

This time-intensive process involved close coordination between Perceptive's scientific/medical and project management teams and the independent reviewers under extremely short timelines. But our dedicated and well-trained teams and reviewers were up for the challenge and adhered to our SOPs to ensure these important processes were followed closely throughout the study.

Challenge 3: Fixed Adjudication Process

Because the sponsor initiated the study following a fixed adjudicator review approach—which results in having fewer reviewers available for both primary reviews and adjudication—additional reviewers needed to be added to meet fast turnaround times. Note this is why Perceptive always recommends a rolling adjudicator approach.

Outcome: FDA Accelerated Approval

Because of Perceptive's expertise in multiple myeloma trial imaging, highly skilled and experienced study managers/reviewers, and our scalable infrastructure, the team overcame each challenge and met the sponsor's timelines.

The regulatory-ready imaging data supported the sponsor's FDA submission and resulted in their compound receiving accelerated approval for the treatment of relapsed or refractory multiple myeloma.

Conclusion

It's important to partner with an imaging core lab who has experience managing the many challenges of multiple myeloma trials, including:

- Complexity of disease presentation
- Nuances of modalities needed for reliable and consistent image acquisition
- Real-world challenges inherent to clinical trials such as the lack of consistent lab results

Perceptive has extensive experience in multiple myeloma imaging, including over 30 pivotal clinical trials that supported 8 regulatory approvals. Our hematology imaging services are led by scientific experts who provide clear guidance on imaging strategy and establish a harmonized approach on the implementation of the IMWG criteria to drive your trial's success.

Contact hello@perceptive.com to learn how the scientific the scientific, medical, and operational expertise behind Perceptive Imaging can drive the success of your hematologic treatment development programs.

perceptive imaging

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