

Article details



Title of article
INSIGHT MM: a large, global, prospective, non-interventional, real-world study of patients with multiple myeloma



Authors
Caitlin Costello, Faith E Davies, Gordon Cook, Jorge Vela-Ojeda, Jim Omel, Robert M Rifkin, Jesus Berdeja, Noemi Puig, Saad Z Usmani, Katja Weisel, Jeffrey A Zonder, Evangelos Terpos, Andrew Spencer, Xavier Leleu, Mario Boccadoro, Michael A Thompson, Dorothy Romanus, Dawn Marie Stull & Vania Hungria



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Trial registration number
NCT02761187

Objectives/rationale



Primary objective
Describe contemporary, real-world patterns of patient characteristics, clinical disease presentation, therapeutic regimen chosen, and clinical outcomes in MM, on a regional and global scale



Secondary objectives
Evaluate the safety and effectiveness of current therapies, the impact of MM on patients' quality of life and HRU, and the associations between patient characteristics, clinical disease presentation, therapeutic patterns, and clinical outcomes

Glossary

EORTC: European Organization for Research and Treatment of Cancer; GHS/QoL: Global Health Status/Quality of Life; HRU: Healthcare resource utilization; MM: Multiple myeloma; PN: Peripheral neuropathy; PRO(s): Patient-reported outcome(s); QLQ-C30: Quality of Life Questionnaire – Core 30 module; QLQ-MY-20: Quality of Life Questionnaire 20-item Multiple Myeloma Module; TSQM-9: Treatment Satisfaction Questionnaire for Medication 9

Study design and treatment, including planned sample size, planned study period and study procedures



Global, prospective, non-interventional, observational study



No study drug provided



No changes in patients' treatment management



Patients to complete PRO questionnaires



15 participating countries



Enrollment period



Follow-up period



Planned sample size



Study overseen by global steering committee of 20 MM specialists and 2 patient representatives

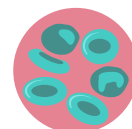
Key eligibility criteria

Age ≥ 18 years



Willing and able to complete PRO questionnaires and sign the informed consent

Newly diagnosed MM: within 3 months of starting treatment



Relapsed/refractory MM: 1–3 prior therapies

Documented data on diagnosis and current/prior therapies received



Outcome measures/endpoints

Baseline assessments:

- Patient demographics
- Clinical disease presentation
- Medical history
- HRU
- PROs: EORTC QLQ-C30 (GHS/QoL subscale), QLQ-MY-20 (single item on PN), and TSQM-9



Quarterly assessments:

- Disease management
- Treatment effectiveness
- Safety
- PROs: EORTC QLQ-C30 (GHS/QoL subscale), QLQ-MY-20 (single item on PN), and TSQM-9