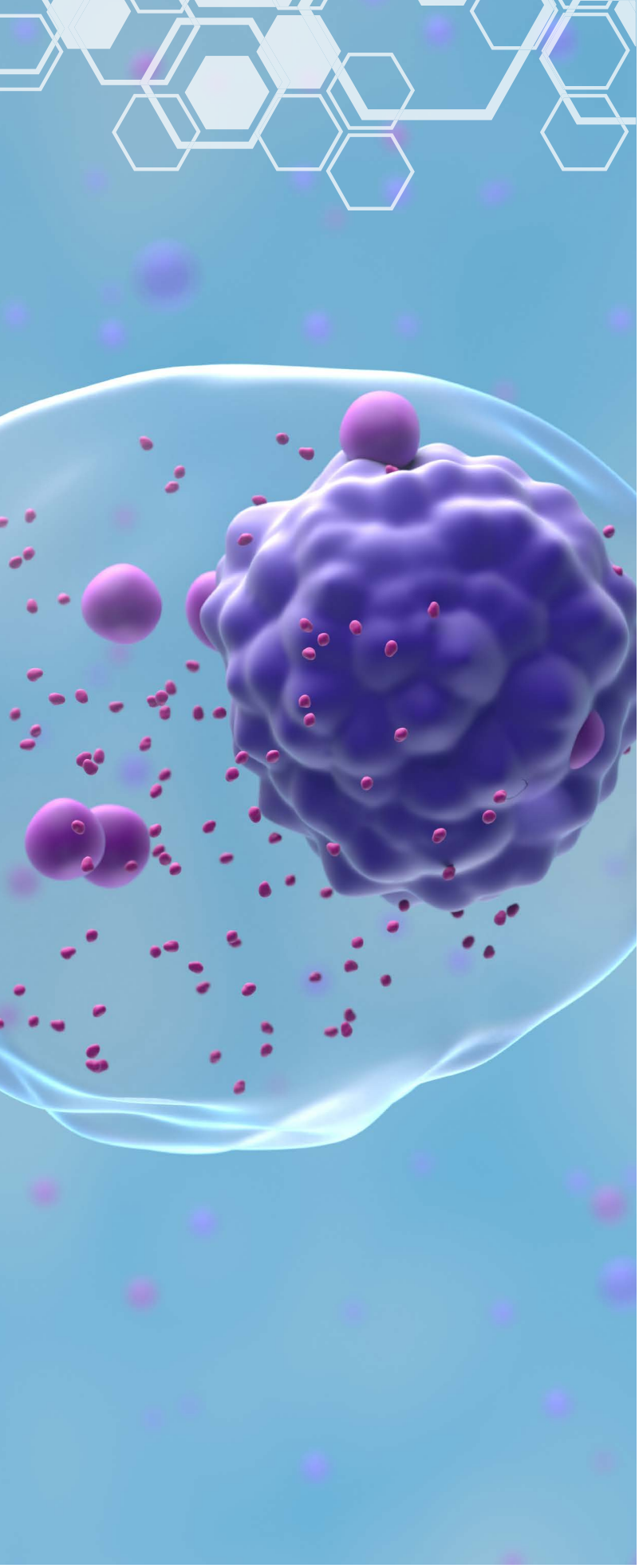
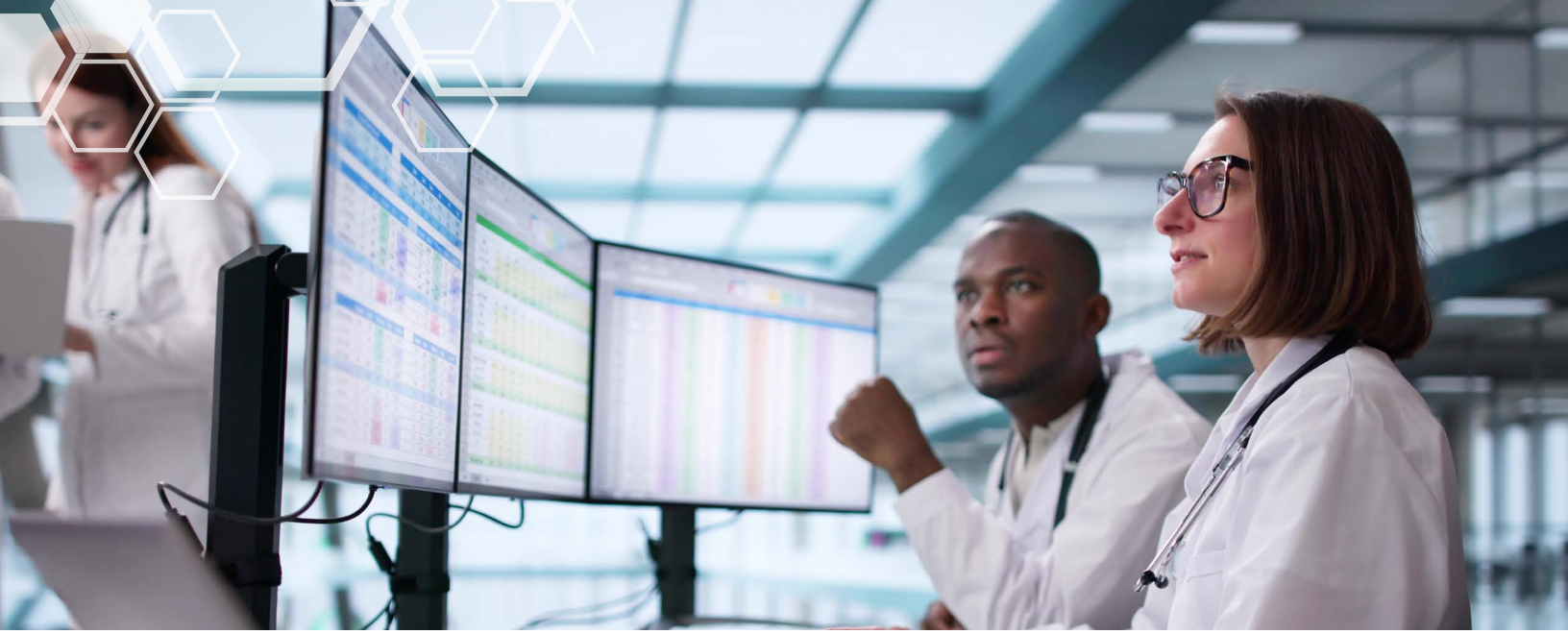


Advance your multiple myeloma clinical trials



Multiple myeloma (MM) is a malignant plasma-cell neoplasm.

Clonal plasma cells accumulate in the bone marrow and can impair normal blood-cell production, weaken bone and produce monoclonal proteins detectable in blood or urine. Disease burden and presentation vary among patients, including marrow and extramedullary involvement.



Symptoms and diagnosis

- **Symptoms:** Some people have no symptoms at diagnosis. When active disease causes symptoms, common features include bone pain or fractures, fatigue, recurrent infections, anemia, renal impairment and hypercalcemia.
- **Diagnosis:** Evaluation may include blood and urine studies, bone marrow aspiration and biopsy, cytogenetic and biomarker testing, and imaging, as specified by the protocol.

Patient experience and treatment options

Multiple myeloma (MM) can significantly affect quality of life, with symptoms and disease-related complications making everyday activities more challenging.

MM is generally considered treatable but remains incurable for most patients. Advances in treatment have enabled many patients to achieve prolonged periods of remission. However, relapse remains common, and patients may require multiple lines of therapy over the course of their disease.

Treatment decisions are individualized based on disease characteristics, prior treatments and responses, overall health and fitness, treatment-related toxicities and patient preferences

Current treatment regimens often combine agents from different classes. Treatment selection and sequencing depend on the disease setting, prior therapies, patient factors and local availability.

Options include:

- Immunomodulatory drugs (IMiDs), such as lenalidomide and pomalidomide.
- Proteasome inhibitors, such as bortezomib, carfilzomib and ixazomib.
- Monoclonal antibodies, such as daratumumab, isatuximab and elotuzumab.
- Other agents, including corticosteroids and exportin-1 inhibitors (e.g., selinexor).
- Cellular and immune therapies, including autologous stem-cell transplantation, CAR T-cell therapy and bispecific antibodies.

Eligible patients may receive high-dose therapy followed by autologous stem-cell transplantation. Suitability and sequencing depend on the treatment plan and patient factors.

Maintenance therapy may be used after initial treatment in selected settings. The approach, duration, and balance of benefit and toxicity depend on the treatment context and patient factors.

In an era where the combination of speed and expertise is crucial for successful outcomes, the PPD™ clinical research business of Thermo Fisher Scientific has demonstrated substantial global experience in supporting studies ranging from first in human to global registrational Phase III precision medicine studies and adaptive study designs.

Choosing a CRO service provider that has the expertise with multiple myeloma clinical trials is critical for success

Multiple myeloma studies demand more than broad oncology experience. Competitive enrollment, complex response assessment, biomarker-intensive protocols and evolving treatment pathways require teams that understand the disease and can translate that expertise into reliable execution. From protocol planning through enrollment, data quality and delivery, our teams bring disease-area knowledge to the decisions that matter most.

Why clinical development remains complex

Most patients experience sequential relapses and require multiple lines of therapy. Development programs must navigate an increasingly competitive treatment environment while maintaining rigorous disease assessment, biomarker and laboratory strategies, and patient access.

Expertise in managing multiple myeloma clinical trials

We combine disease-area expertise with operational scale, integrated science and enrollment strategies for multiple myeloma studies.

We have 3,450+ hematology and oncology experienced staff and 1,200+ resources that are experienced in multiple myeloma, across all regions.

As of Sept. 30, 2026	HemOnc experience (# resources)	Multiple myeloma experience (# resources)
Clinical Research Associate (CRA)	2815	896
Clinical Team Manager (CTM)	439	212
Project Lead (PL)	185	94
Oversight Director (OD)	51	35
Total	**3490**	**1237**

Challenges in multiple myeloma clinical trials

- **Competitive landscape:** Multiple treatment options compete for the same sites and patients.
- **Response assessment:** Complex criteria require disciplined review of patient-level data.
- **Laboratory intensity:** High sample volumes and specialized testing increase operational complexity.
- **Treatment-specific oversight:** Emerging modalities may require specialized medical, safety and operational pathways.

Our solutions and capabilities

- **Dedicated recruitment task force:** Our specialized team, led by a patient recruitment and engagement lead (PREL), manages enrollment strategies, updates trackers, and communicates progress through emails, calls and newsletters.
- **Client engagement:** We engage medical monitors and patient advocacy groups (PAGs) to support collaboration with clients.
- **Site engagement:** We use robust country and site mix strategies to recommend best sites based on our experience, knowledge and site partnerships.
- **Early clinical team involvement:** We track eligibility and provide patient status updates early in the study meeting regulatory documentation requirements.
- **Disease assessment:**
  - o Clinical research associates (CRAs) trained on how to review all data to ensure unique patient criteria for response assessment is met.
  - o Our disease assessment quality control (DAQC) tool cuts medical review time by 25%. This DAQC tool can perform a QC of sites declared response of disease and programmatic response based on data entered in electronic data capture.

We have disease specific training modules, HemOnc training academy, cell and gene therapy academy, and Accelerator™ Drug Development university.



Accelerating patient recruitment

- **Strategic enrollment solutions:** We use tailored strategies to address recruitment challenges, including early assignment of key clinical staff.
  - o We integrate patient advocacy groups (PAGs), HealthUnlocked engagement and health care provider panel referrals into the overall recruitment strategy.
- **Proactive engagement:** We engage clinical teams and stakeholders to ensure smooth recruitment processes.

Ensuring quality data

- **Central vs local lab:** Given the number of lab samples required, we prefer central lab analysis done in parallel to local analysis (especially for FISH) to ensure consistency and reduce mistakes.

AI and digital innovation portfolio

Selected AI and digital capabilities can help teams identify patients, anticipate execution risk and streamline study delivery:

Patient match AI + smart screening

Uses consented patient data to size feasible populations, refine eligibility and identify targeted cohorts. Supports stronger feasibility, site strategy and recruitment planning.

Clinical trial forecasting suite

Uses deep-learning models to forecast enrollment and site activation scenarios, supporting earlier risk visibility. Updates scenarios as new information becomes available.

StudyGage

Predicts how likely patients are to participate in a study and identifies the design elements creating the most burden. Helps teams test alternatives and improve enrollment assumptions before launch.

CRA assistant

Helps clinical research associates prioritize issues and surface relevant study information to support more focused monitoring and data review. Reduces administrative burden so more time can be spent on site quality and intervention.

These capabilities complement the existing Patient First Digital solutions + PREL patient-identification model and predictive enrollment dashboards highlighted above.

Drug approval support

Since 2013, we have supported drug approvals that are now considered standard of care. We have also been involved in obtaining approval for **53% MM treatments globally.**

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Market approvals

MM market approvals

- 11 US Food and Drug Administration
- 11 European Medicines Agency
- 5 China's National Medical Products Administration
- 5 Health Canada
- 3 Therapeutic Goods Administration
- 4 Pharmaceuticals and Medical Devices Agency in Japan

Our experience in the last five years

- **Studies:** Our experienced global team has worked with biopharma and biotech clients on managing 39 active multiple myeloma studies, including in cell therapy One phase III study.
- **Global reach:** We have conducted trials across +50 countries, all regions, utilizing 998 sites and enrolling 7,242 patients.

Hematology/oncology* studies	**774** studies	**167,256** participants	**26,408** sites
Multiple myeloma studies*	**39** studies	**7,242** participants	**998** sites

*Studies managed till date 01 Aug 2021 – 31 Mar 2026

Our experience spans across various phases

Category	Studies managed by our team (01 April 2021 to 31 March 2026)	
	Hematology/oncology	Multiple myeloma
Phase I	173	11
Phase II	155	5
Phase III	157	10
Phase IV	17	2
Other	272	11
Total	**774**	**39**

Other includes Phase IV, registry, observational or consulting agreements managed by us.

Total sum of sites across studies does not represent number of unique sites

Data reflects baseline numbers of sites/participants. Actual numbers of sites/participants may by less than baseline values due to studies still open.

*Studies included blinded independent review committees (IRCs). Primary endpoints included progression-free survival (PFS) and minimal residual disease (MRD)-negative complete response (CR). Secondary endpoints included complete response rate, overall survival (OS), overall response rate (ORR), duration of response (DOR), time to progression, time to next treatment (TTNT), quality of life (QoL), EORTC QLQ-C30, EORTC QLQ-MY20, EQ-5D-5L, safety and sustained MRD negativity.

Success story

In a global Phase III relapsed or refractory multiple myeloma (RRMM) registrational study, we supported the enrollment of more than 930 participants across approximately 262 sites in over 30 countries, including Japan.

- The study achieved its enrollment target three months ahead of schedule, successfully managed enrollment and participant diversity challenges and completed its second interim-analysis database lock on time.
- The program also underwent successful regulatory inspections, and we supported the client's FDA New Drug Application (NDA) filing and subsequent approval for the RRMM asset.





Thermo Fisher Scientific contributions and investments in oncology and multiple myeloma research advance treatments for patients

Experienced staff with 1,200+ multiple myeloma experts

Advanced diagnostic and biomarker support

- The Binding Site Diagnostics: Freelite® assays + EXENT® mass spectrometry for sensitive M-protein detection and MRD-aligned monitoring
- Oncomine™ genomics: Comprehensive genomic profiling to enable biomarker-driven enrollment and precision stratification
- CAR-T solutions: Instruments and consumables supporting development and manufacturing of next-generation MM cell therapies

Embedded medical and ocular oversight

Ongoing expert review with trending tools: Keratopathy Visual Acuity (KVA) grading calibration, ophthalmology pathways and centralized oversight designed for belantamab-associated ocular risk.

AI-enabled patient identification and recruitment governance

Patient First Digital solutions (PFDS) + patient recruitment and engagement lead (PREL) model leveraging electronic health records (EHR), claims, pharmacy data and predictive enrollment dashboards to increase on-time delivery. Flexible site networks, Just in Time (JIT) community centers and home trial services for Phase I to Phase IV studies.

Community oncology expansion via PPD Select

Activation of MM-capable Just in Time (JIT) community sites and under-represented markets to reduce academic saturation and protect US enrollment commitments.

Enhanced patient retention strategies

Our patient centric services reduce the burden of participation with: home healthcare services, telemedicine, digital tools, transportation assistance, reimbursement support



Let's partner to move your multiple myeloma clinical trials forward. Visit ppd.com to learn more.

For more information about multiple myeloma and our clinical trial management capabilities, please contact our disease area lead:

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Executive director, project delivery
Email: Melanie.owen@thermofisher.com
Mobile: +1-513-312-0509

Learn more at ppd.com/therapeutic-expertise/oncology-and-hematology-cro/

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