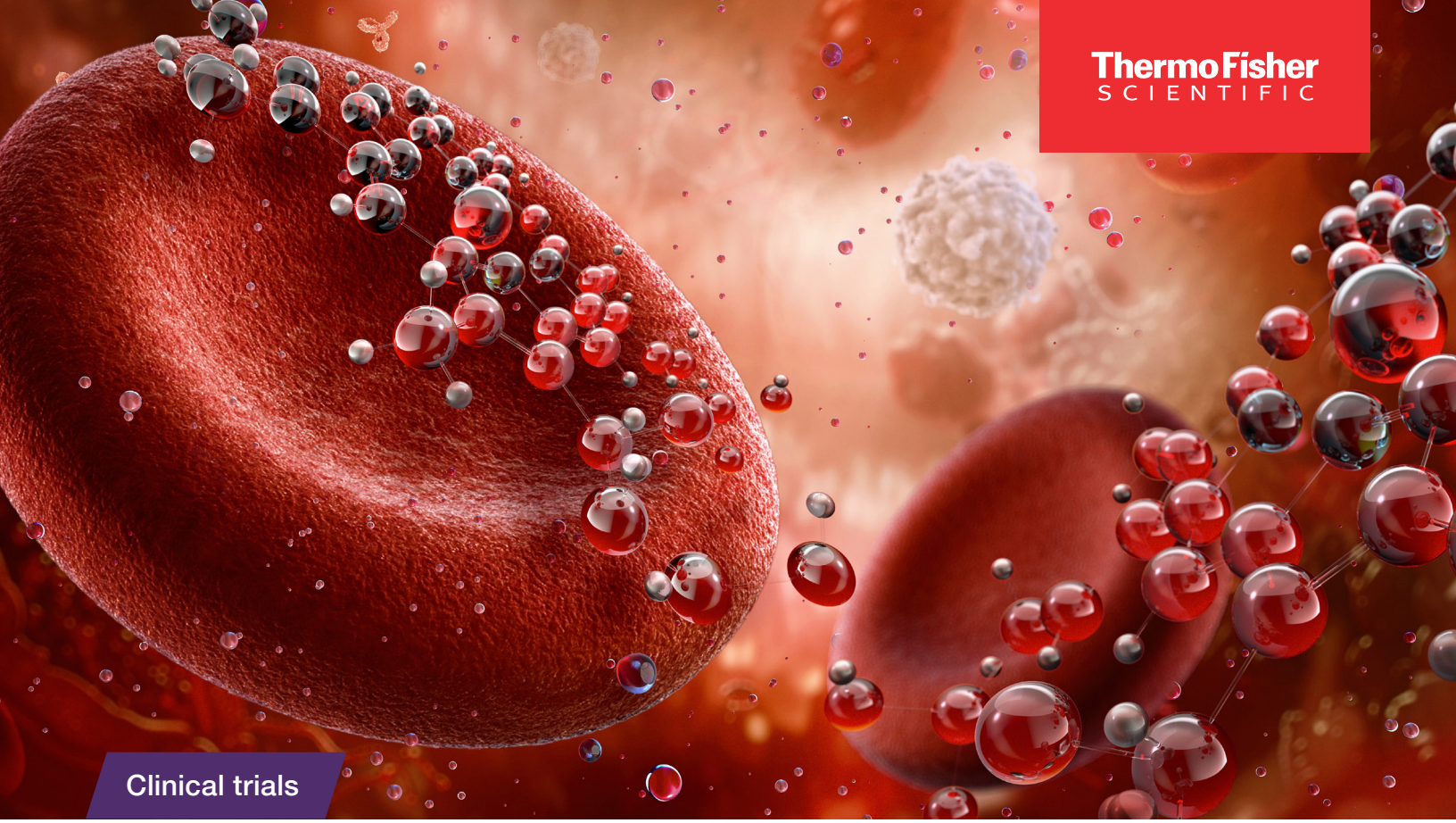


Expert guidance and active site collaboration to advance your myelodysplastic syndromes clinical trials

ppd

Advancing MDS research

Myelodysplastic syndromes, or MDS, present distinct clinical development. Though somewhat uncommon, MDS primarily affects older adults and is often associated with anemia, transfusion dependence, frequent monitoring and risk of progression to acute myeloid leukemia.

MDS has a relatively low incidence rate of four to five cases per 100,000 people. However, certain risk factors can increase the likelihood of developing MDS, including prior chemotherapy, genetic disorders, smoking, radiation exposure, and exposure to certain chemicals. Patients with MDS are also at risk of progressing to acute leukemia.

The Revised International Prognostic Scoring System classifies patients with MDS into five risk groups — from very low to very high — based on specific diagnostic criteria. These categories are used to predict the risk of progression to acute myeloid leukemia and overall survival. Median survival varies widely by risk group, from 8.8 years for low-risk MDS to 0.8 years for very high-risk MDS.

Given the challenges, complexities and risk of progression associated with MDS, there is a critical need to advance clinical trials in this field and explore new treatments. Our expertise and engagement with research sites offer a unique opportunity to advance clinical trials in this field, aiming to improve patient outcomes and quality of life.

Conducting MDS clinical trials presents several distinct challenges. Because MDS is often underrecognized and underdiagnosed, patients may experience delays in diagnosis and treatment. Many patients are also older and are reluctant or unable to make frequent hospital visits, preferring to receive transfusions at home or at nearby clinics. This can create documentation gaps and affect data accuracy, especially when transfusions are not reported before a data lock.

Successful enrollment requires carefully designed inclusion and exclusion criteria, as well as strategic site selection. MDS studies involve a high volume of laboratory samples and bone marrow biopsies, making coordination between local and central laboratories essential to ensure consistency, reduce variability, and minimize errors.

Long follow-up periods — sometimes spanning several years — can further complicate data collection and put patient retention at risk.

For sponsors, these factors make MDS trials more complex across every stage. Successful studies require deep therapeutic expertise, thoughtful protocol design, strong patient and caregiver support, strategic site selection, and close coordination across local and central laboratory teams.

Our experience managing these complexities, combined with strong research site engagement, enables sponsors to advance MDS treatment development and support better outcomes and quality of life for patients.

Our MDS experience in the past five years:

18 studies

1,622 patients

901 global sites

Phase	Number of studies
Phase I	2
Phase II	8
Phase III	6
Non interventional	2

Leverage significant myelodysplastic syndrome experience that spans the globe

Roles	Global oncology experienced staff	Global Myelodysplastic Syndrome (MDS) experienced staff	% of oncology staff with MDS experience
CTM	1499	100	6.7%
OD	174	20	11.5%
PL	754	43	5.7%
CRA	3955	546	14%
ACRA	702	95	13.5%
Grand Total	**7,084**	**804**	**6.7%**

Both large biopharma and smaller biotech companies have turned to us to manage and deliver MDS studies across all phases and regions.

Our protocols have included both advanced and low-risk MDS populations, including newly diagnosed and relapsed/refractory patients. We have contributed to the approval and marketing authorization of two compounds in this indication and successfully supported regulatory inspections at both the study and site levels, including by the FDA, EMA, MHRA and PMDA.

Our MDS trials have engaged investigators from 44 countries across five regions participated in our trials, reflecting broad global experience in this therapeutic area.

To reduce the burden on older patients, we implement home health care professional services that enable blood sample collection for pharmacokinetic (PK) and biomarker analyses in the home setting. This approach improves patient convenience and helps increase overall retention.

Keys to successful MDS clinical trials

Drawing on our experience with hematologists from previous studies, as well as our familiarity with the sites and their capabilities, we conduct expedited feasibility assessments using abbreviated questionnaires and remote pre-study evaluations. This approach significantly reduces the time from final protocol to site qualification.

During enrollment, we work closely with each site to identify potential challenges and implement tailored solutions. Our support includes:

- Facilitating referral networks
- Encouraging country-level peer-to-peer discussions
- Collaborating with patient advocacy groups
- Introducing targeted initiatives to accelerate recruitment

Data cleaning and reconciliation are also top priorities, helping ensure high-quality, robust data for interim and final regulatory submissions. We place particular focus on key endpoints, such as transfusion outcomes and PK data, enabling timely, reliable delivery of results.

Our end-to-end solutions for MDS clinical trials ensure that all aspects of the trial process are expertly managed, from initial design to final regulatory approval, ultimately accelerating the development of new and effective MDS treatments.

Your trusted partner in MDS development

Our end-to-end solutions for MDS cancer trials ensure that all aspects of the trial process are expertly managed — from initial design to final regulatory approval — ultimately accelerating the development of new and effective MDS cancer treatments.

A Global Network of > 1,000 experienced Hematologist, with Indication Specific expertise

Characterization, endpoint determination, and patient recruitment expertise

Optimized, data driven country and trial site selection

Site activation, enrollment, and retention strategy

Deep understanding of key protocol components impacting enrollment

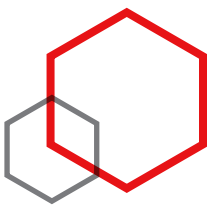
Strategic Development consulting expertise in core disciplines (CMC, toxicology, pharmacology)

Clinical and Regulatory Strategy consulting

Data Management and hematology expertise in biostatistics, quality and regulatory expertise

Relationship with key opinion leaders by Hematology specialty

Support services for optimizing access and minimizing patient burden



Our enrollment and retention strategies

Easing enrollment and increasing retention with patient-centric services

Clinical trials in rare disease are burdensome for the patients and their caregivers. Our host of supportive concierge services reduces the burden for both sites and patients and makes participation in trials easier by offering:

- Telemedicine and Home Health care Services
- Transportation Coordination and Verification
- Flexible Reimbursement Options
- Wearable and Mobile Pagers

These services help produce timely and high-quality data while saving patients time and cost. Our patient-centric approach has led to more than 90% patient retention over five years in recent clinical trials.

We combine deep therapeutic expertise with advanced imaging, biomarker, and data technologies to accelerate innovation in head and neck cancer research.

Our integrated approach ensures precision, consistency and speed across every phase of clinical development. Together, we bring life-changing therapies to the patients who need them.

Let's accelerate your MDS clinical trials.

Visit ppd.com to get started

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