Expertise to accelerate your myelofibrosis clinical trials

Myeloproliferative neoplasms (MPNs) are a group of rare chronic blood cancers characterized by clonal proliferation of bone marrow stem cells, resulting in increased platelets, red blood cells, or white blood cells. There are three major myeloproliferative BCR-ABL1-negative neoplasm subtypes—polycythemia vera, essential thrombocythemia and myelofibrosis (MF). Of the three, MF is the most aggressive type of MPN, with worse prognosis than the other two.

Myelofibrosis is a rare type of bone marrow cancer that disrupts the body's normal production of blood cells, leading to extensive scarring in the bone marrow, anemia, weakness, fatigue, and often an enlarged spleen.

Patients with MF face significant impacts on their quality of life, making daily activities challenging due to severe fatigue and other symptoms. The elderly population, often with other comorbidities, is particularly affected.

Treatment approaches continue to evolve, along with an interest in new treatment options, particularly for patients with low-risk or early-stage disease, from a "watch and wait" approach to active treatment.

However, drug developers face lingering challenges.

- **Recruitment difficulties:** Enrolling patients with complex medical needs and ensuring early tracking of transfusion dependency.
- **Site engagement:** Low engagement from clinical sites and the need for early involvement of clinical teams.
- **Protocol deviations:** High incidence of adverse events (AEs) and serious adverse events (SAEs) leading to dose and visit delays.

The PPD™ clinical research business of Thermo Fisher Scientific is your partner in accelerating development—combining global expertise, operational excellence, and a robust network of hematology sites to support recruitment, retention and trial success.

In the past five years, our expert myelofibrosis cancer team has supported:

823+
Patients

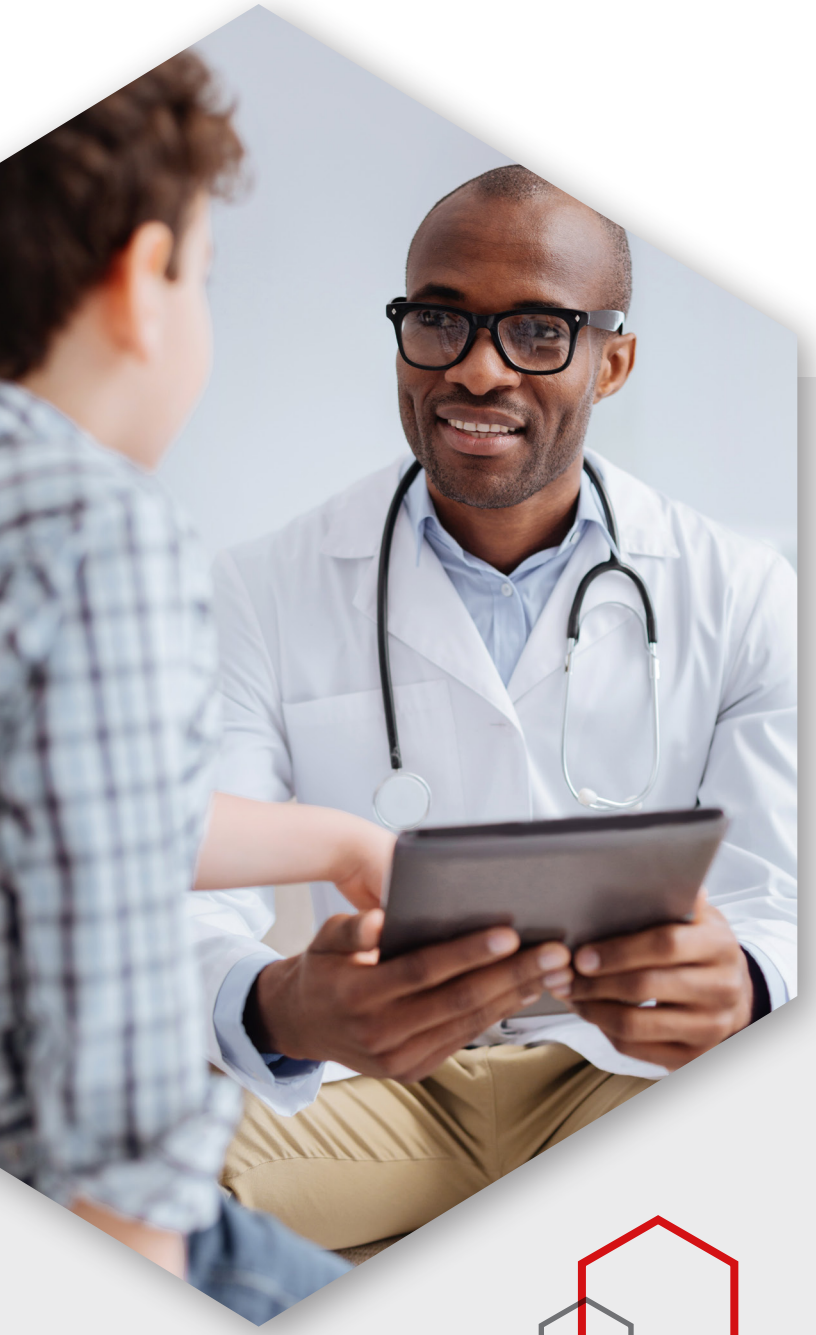
12+ MPN cancer trials, including more than eight MF studies (from early to late stage development)

333+
Global sites

26+
Countries

When you partner with us on your myelofibrosis trials, you gain expertise in:

- **Client engagement:** We involve medical monitors and patient advocacy groups to ensure robust client collaboration.
- **Central vs. local lab management:** Due to the high number of required lab samples, we prefer central lab analysis done in parallel to local analysis to ensure consistency and reduce mistakes.
- **Tracking and documentation:** Early tracking of transfusion dependency and patient eligibility ensures high-quality data for regulatory documentation.



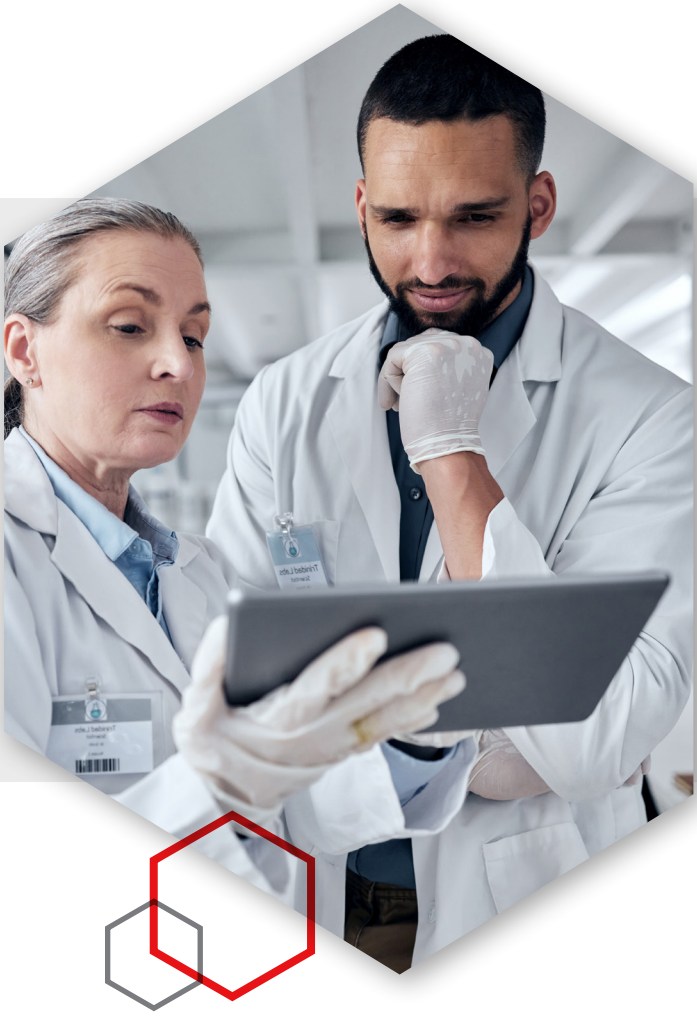
Easing recruitment challenges with innovative enrollment strategies

Enrolling patients in oncology clinical trials is notoriously difficult, and many promising studies are delayed or fail because of recruitment challenges. These issues arise from patient-related, physician-related, trial-related, and system-level barriers. We have proven strategies to address these challenges in order to provide successful clinical trial outcomes.

- **Dedicated recruitment task force:** Our specialized team, led by a recruitment lead, manages enrollment strategies, updates trackers, and communicates progress through various channels (e.g., emails, calls, newsletters).
- **Site engagement:** We actively review and re-evaluate enrolling sites, adding new regions as necessary to enhance site engagement.
- **Early clinical team involvement:** We ensure eligibility tracking and patient status updates early on, meeting regulatory documentation requirements.
- **Strategic enrollment solutions:** We implement tailored strategies to address recruitment challenges, including early assignment of key clinical staff.
- **Proactive engagement:** We continuously involve clinical teams and stakeholders to ensure smooth recruitment processes.

ThermoFisher SCIENTIFIC

Talk to us about how we can accelerate your clinical trials with our expertise with myeloproliferative neoplasms (MPNs) and myelofibrosis (MF).



Learn more at **ppd.com**

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