Clinical trials

Hematology | Oncology

ppd

Navigating the complex landscape of hematology and oncology clinical trials with comprehensive solutions

With over 30 years of dedicated service in the field of clinical drug development, the PPD™ clincal research business of Thermo Fisher Scientific understands the unique challenges that the world of oncology clinical trials presents. In an ever-shifting landscape marked by rapidly changing standards of care, intense competition for qualified sites and patients, and stringent regulatory requirements, we stand out as a beacon of reliability and innovation.

We pride ourselves on our deep understanding of the regulatory intricacies that govern this complex field. We recognize the challenges of:

- Diversity and inclusion goals
- High data volume collection demands
- Long term follow-up requirements imposed by regulators and payors

Our ability to navigate this challenging terrain is what truly differentiates us. We also believe in the power of caring, and that's why we place patient centricity at the heart of everything we do.

Our commitment to excellence extends to our broad global clinical site network, ensuring that patients everywhere have access to cutting-edge treatments. We know that success in oncology clinical trials requires more than just expertise; it requires a genuine concern for the well-being of patients.

In addition to our extensive hematology and oncology knowledge, we offer specialized capabilities:

- Phase I clinical trials
- Cell and gene therapy
- Rare disease research
- Benign hematology

We can leverage expanded resources and capabilities to provide efficiency and innovation in clinical trials. We don't just conduct trials; we pioneer advancements, foster inclusion, and strive for excellence in every aspect of our work. Join us on this transformative journey, where experience meets innovation, and together, we make a difference in the world of oncology.

Hematology | oncology: Addressing unique needs in a complex landscape

In the intricate world of hematology and oncology development, finding a partner who possesses the expertise and a deep understanding of the distinctive intricacies and opportunities within this therapeutic domain is paramount.

We stand as a tried-and-true global leader in oncology clinical research, boasting an impressive track record that includes over **750** hematology/oncology studies conducted globally. Our extensive experience spans across **175,000+** patients at **35,000+** sites, operating in more than **100** countries. This impressive portfolio encompasses not only conventional clinical trials but also real-world and post-approval studies, all accomplished within the last five years.

Our breadth of experience extends to the management of clinical trials in complex indications. We specialize in benign hematologic disorders, hematologic malignancies, and various oncology diseases, including rare tumor types, cancer-related pain, and supportive care. Our commitment to excellence remains unwavering as we navigate the intricate landscape of hematology and oncology development, striving to provide tailored solutions that meet the unique needs of this dynamic field.

Expertise spanning a broad range of indications:

Hematological Disorders	Skin Cancers	Solid Tumors	Rare Diseases	Others
Acute lymphoblastic leukemia	Basal cell carcinoma	Biliary tract cancer	Amyloidosis	Astrocytoma
Acute myeloid leukemia	Melanoma	Bladder cancer	Cholangiocarcinoma	Cachexia
Autoimmune hemolytic anemia*	Merkel cell carcinoma*	Breast cancer	Glioblastoma	Graft vs. Host Disease
Beta-thalassemia*	Squamous cell carcinoma	Colorectal cancer	Glioma	
Blood coagulation disorders		Esophageal cancer	Hepatic veno-occlusive disease	
Chronic lymphocytic leukemia		Gastric cancer	Neuroendocrine tumors	
Chronic myelogenious leukemia		Gastro-esophageal	Pediatric brain cancer	
		adenocarcinoma		
Cutaneous T-cell lymphoma		Head and Neck Cancer	Rhabdomyosarcoma	
Follicular lymphoma		Hepatocellular carcinoma	Systemic mastocytosis	
Hemolytic uremic syndrome*		Non-small cell lung cancer		
Hemophilia A & B*		Ovarian cancer		
Immune thrombocytopenic purpura*		Pancreatic cancer		
Large B cell diffuse lymphoma		Prostate cancer		
Multiple Myeloma		Renal cell carcinoma		
Myelodysplastic syndromes*		Small cell lung cancer		
Myeloproliferative neoplasms*		Thyroid cancer		
Non-hodkin's lymphoma		Uterine cancer		
Paroxysmal nocturnal hemoglobinuria*				
Polycythemia vera*				
Primary immune thrombocytopenia*				
Sickle cell trait / sickle cell anemia*				
Waldernstrom macroglobulinemia*				

*Rare Disease

Table 1: Industry leading expertise across a full range of cancer therapies, from Immuno-oncology and targeted treatments to novel and emerging therapies, including cell and gene therapies.

Delivering tailored expertise for complex drug development challenges

Proven ability to provide specialized capabilities that are adapted to meet the complex demands of innovative drug development

Rare disease and Pediatric expertise

Our team of experts is your trusted guide for meticulously planning and executing rare and pediatric oncology clinical trials. With a wealth of experience spanning all phases, indications, and therapeutic areas, including a portfolio of over 500 clinical studies, our cross-functional team at the Rare Disease and Pediatrics Center of Excellence is equipped to provide innovative, patient-centric solutions to navigate the intricacies of these trials. We understand the unique considerations and complexities involved in rare and pediatric oncology research.

Innovative trial designs with adaptive and master protocols

Recognized as pioneers in innovative trial design, including adaptive designs and master protocols, we have successfully implemented over 40 such methodologies in the field of oncology. These innovative trial designs play a pivotal role in early-phase drug development, where decisions carry far-reaching consequences. Leveraging adaptive trial designs allows us to uncover potential issues earlier in the process, enabling faster “go or no-go” decision-making and instilling greater confidence in trial outcomes. Our extensive experience in designing and operationalizing these innovative trial approaches, facilitated through our Adaptive Design and Master Protocol Working Group, empowers you with quicker access to more robust data.

Immuno-oncology, cell, and gene therapy expertise

With decades of experience in managing cell and gene therapy clinical trials and supporting over 160 immuno-oncology studies, including 137+ in cell and gene therapy across diverse tumor types and therapies involving over 33,000 patients, we stand as a true leader in this field. Moreover, we offer comprehensive laboratory support for cell and gene therapies, including CAR-T. Our Cell and Gene Therapy Centers of Excellence ensure that our project teams and clients stay informed about the competitive landscape, efficient adaptive designs, and the dynamic regulatory environment surrounding immunotherapies.

A leader in early phase oncology development

As your early development partner, we combine expertise with global reach to:

- Reduce timelines and improve success rates.
- Optimize resource allocation towards more promising indications or assets.
- Enable confident early elimination of less effective drug candidates.

Our dedicated early development oncology experts provide insights and strategies for protocol design, statistical considerations, regulatory agency consultations, and early operational interventions. Together, we expedite the path to groundbreaking oncology discoveries while minimizing risks and maximizing success.

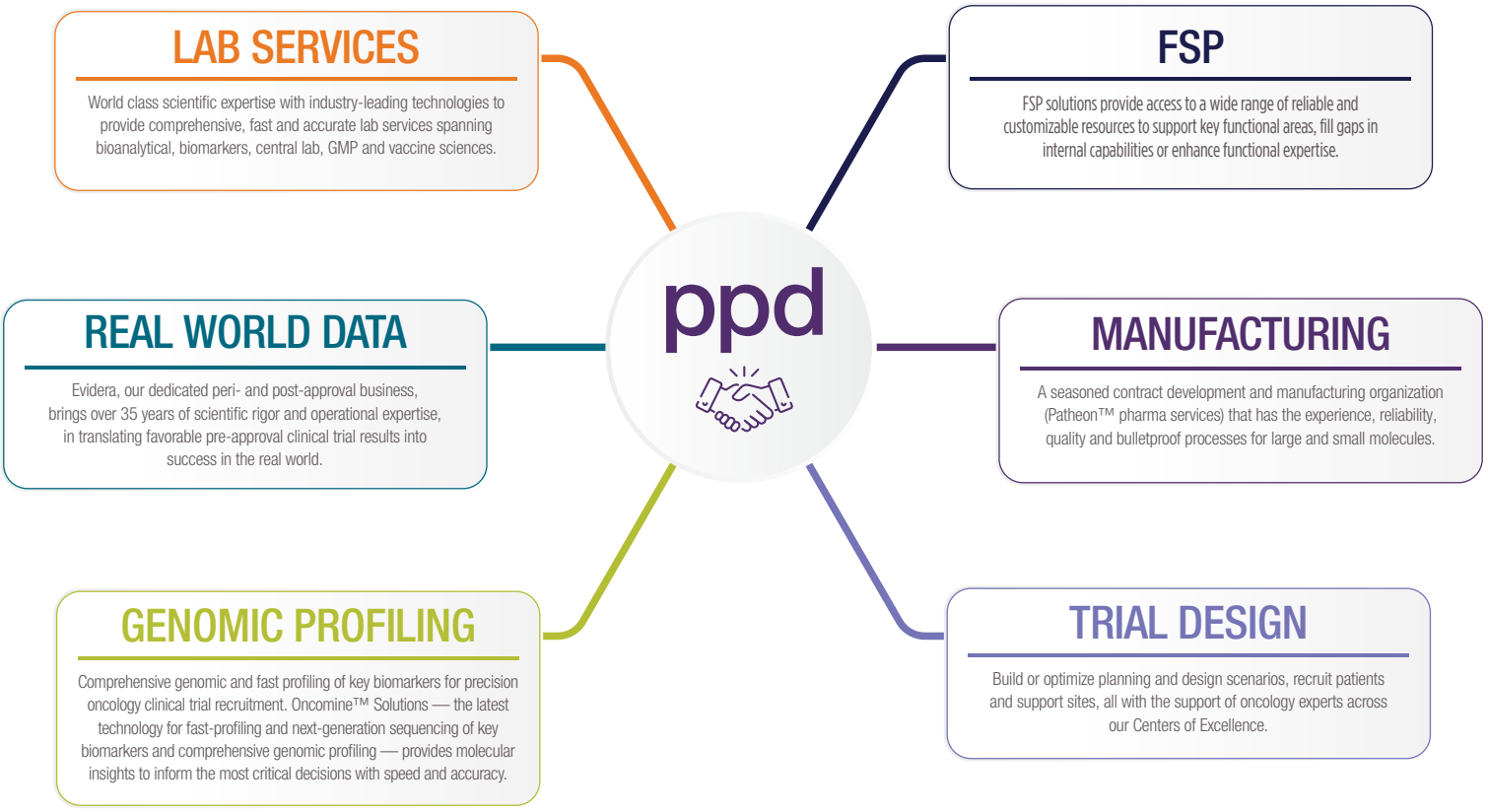
A dedicated and experienced team to ensure operational excellence

Knowledgeable experts with international regulatory expertise across a wide variety of hematology / oncology therapies and indications. These experts lead the development of study-specific regulatory submission plans, identify potential issues up front and ensure a robust data package is submitted to the relevant regulatory authorities. They actively manage the submission process to ensure timely study start up and execution.

Delivering complex clinical trials with comprehensive oncology capabilities

All phases of oncology development — from early drug discovery support and clinical development to market access and commercial strategy with innovative technologies and solutions — require dedicated teams equipped with the knowledge, experience, and solutions to reduce patient burden and make trial participation viable for patients while achieving optimal doses, accelerating timelines, and maximizing cost savings.

By partnering with us, you gain access to the latest oncology technologies, world-class laboratories, contract development and manufacturing organization (CDMO) services and peri- and post-approval services.



Rapid recruitment and participant access for hematology | oncology trials

We excel in delivering studies on schedule through our proven trial enhancement approach. This four-part strategy ensures robust site enrollment and performance and encompasses:

Consultation and early engagement

Our experts, well-versed in the therapeutic domain, engage with clients prior to protocol development or provide guidance on existing protocols to minimize amendments and lower expenses.

Data-driven analysis

Analytics and expert recommendations improve forecasting to optimize both the protocol and the trial and to mitigate risk before a study begins.

Investigator feasibility and site selection

We recommend sites and investigators with a track record of successfully conducting similar studies and meeting patient recruitment timelines.

Ongoing feasibility and optimization

We establish a feedback loop to assess the effectiveness of the trial optimization strategy, making necessary adjustments to achieve time and cost efficiencies.

Alleviating burdens with decentralized approaches

Our aim is to decrease clinical trial burden and increase flexibility for hematology and oncology patients and their loved ones. For both care and research, bringing patients into physical clinics can be challenging, especially for children or those with limited mobility. Innovative, flexible protocols–combined with digital and decentralized trial technologies–offer new ways to reach, recruit and retain hematology and oncology patients. We are able to meet patients where they are and simplify participation with tools such as mobile sites, wearables, telehealth and e-consent. The flexibility of these options allows for enhanced recruitment, increased patient diversity and removes geographical barriers by bringing the site to the patients.

Oncology enrollment enhancement the just-in-time approach

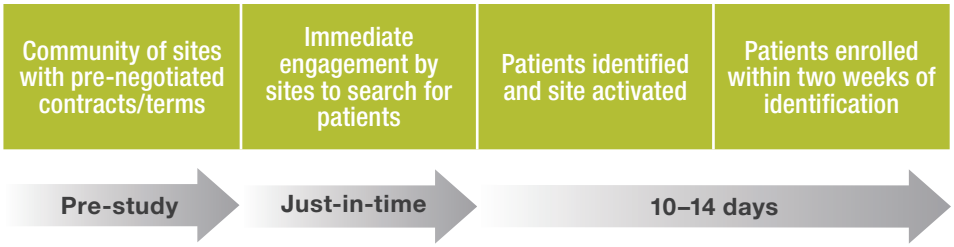
Oncology clinical trials represent a special challenge for biopharmaceutical companies. When oncology research sites enroll, it takes an average of more than eight months from protocol outreach to site activation. Some 60 percent of sites never enroll and 40 percent of ongoing trials never meet enrollment targets*.

300+
pre-qualified sites

1,000+
investigators

Zero
non-enrolling sites in the just-in-time community

Oncology enrollment enhancement uses a just-in-time methodology to jump-start study enrollment. We provide confirmed availability of pre-identified patients from pre-qualified sites in our community of over 300 sites with over 1,000 research-experienced investigators. This turnkey service augments your traditional trial approach and provides the first study subject within two weeks of patient identification.



* https://www.forbes.com/sites/judystone/2015/01/06/how-can-we-encourage-participation-in-clinical-trials/#1dc9f1ac4d0c

Benefits

Diversity
Just-in-time sites are concentrated in ethnically diverse areas

Patient-centric
Exposing more trial options to patients while allowing sites to focus on studies for which they have patients

Efficiency
Improved efficiencies/volume through protocol stacking

Performance
Opportunity to accelerate overall study performance

Risk Management
Mitigate risk from non-enrolling sites; risk mitigation strategy is available from day one

Our sites with hematology/oncology experience: global

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