Accelerate your clinical trial with our expertise in melanoma drug development

ppd

Disease background information

The global incidence of melanoma has been rising over the past few decades, making it an increasingly common and significant public health concern.

That's compounded by the profound impact melanoma can have on patients and their families — affecting them physically, emotionally, socially and financially. Patients face the genetic and molecular complexity of their disease, along with the limited effectiveness of current treatment options. The need for new therapies that deliver better outcomes is urgent.

Continued research and innovation are critical to developing treatments that are more effective, safer and accessible to melanoma patients worldwide.

At a time when speed and precision matter most, the PPD™ clinical research business of Thermo Fisher Scientific is the partner you can trust to advance your therapeutic development. We combine global medical and operational expertise with a hands-on approach to move your trial efficiently toward success.

With access to an extensive network of experienced research sites and professionals, our team navigates the complexities of global melanoma trials. We also provide patient-focused services designed to streamline recruitment and improve retention.

Together, we can accelerate progress — and bring new hope to patients living with melanoma.

Challenges with melanoma clinical research

The incidence, prevalence and mortality of melanoma remain unacceptably high. Multiple challenges associated with the treatment of melanoma require a multidisciplinary approach, ongoing research, and advancements in medical technology and treatment strategies.

Some key challenges include:

Aggressive nature

Melanoma is highly aggressive and prone to metastasis, increasing treatment complexity.

Psychological impact

Melanoma diagnosis and treatment can significantly affect patients' mental health, requiring integrated psychosocial support.

Immune system interaction

Melanoma can evade the immune system, making immunotherapy less effective in some cases.

Resistance to treatment

Melanoma may develop resistance to chemotherapy and targeted therapies, driving the need for ongoing innovation and new treatment strategies.

Genetic variability

Melanoma tumors exhibit diverse genetic mutations, requiring personalized treatment approaches and precise mutation identification.

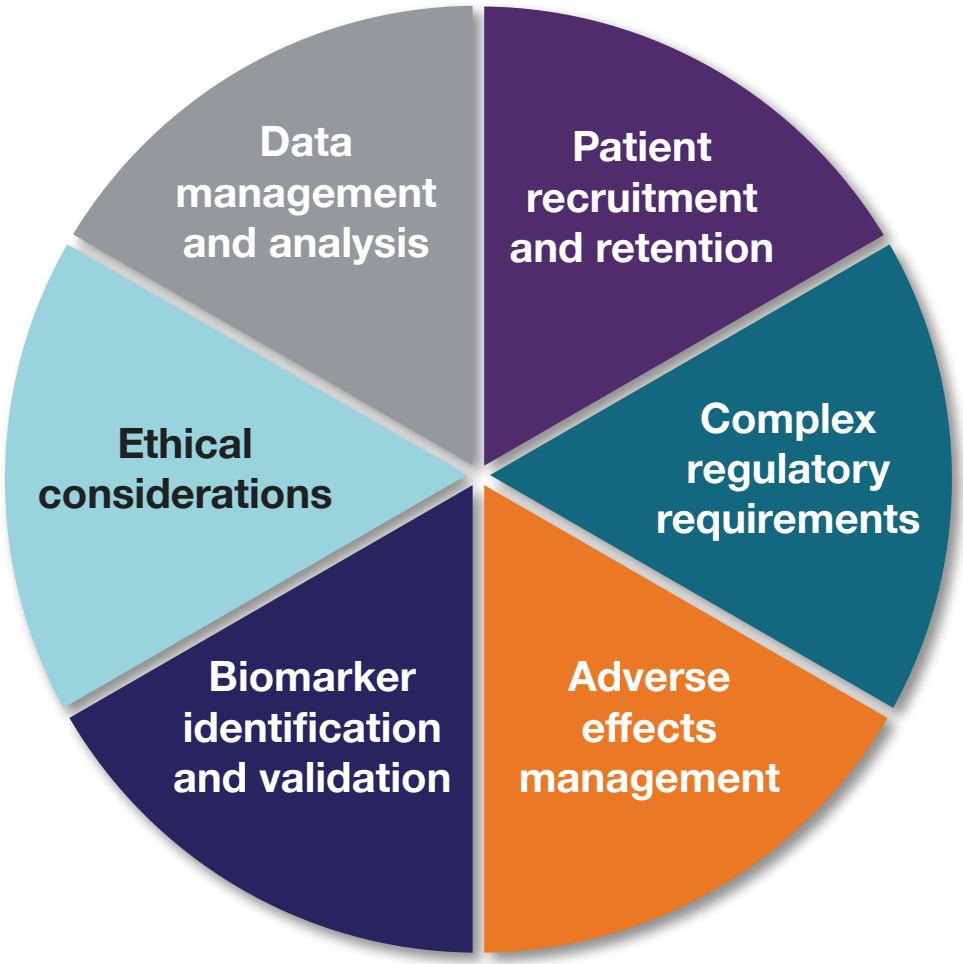
Access to care

Limited access to specialized care and advanced therapies, particularly in rural or underserved areas, can negatively impact patient outcomes.

Challenges with melanoma clinical research

Similarly, researching and developing new treatments for melanoma presents additional challenges that demand robust, innovative and patient-centered strategies.

Addressing these challenges requires a multifaceted approach involving advancements in medical research, improvements in health care systems, and support for patients and their families.



Our experience and expertise

Over the past **10 years** (2015 – 2025), we have contributed to the development of **seven innovative melanoma treatments**.

Our **deep global expertise** in early and late phase oncology, as well as gene and cell therapy, **supports strategic solutions** and **recent successes in melanoma trials**. We tailor our approach to each protocol and **proactively identify and address potential challenges before they impact your study**.

Melanoma studies in the past five years (August 2020 – August 2025)

25+
Studies

4,780+
Patients

1,330+
Global sites

57
Countries

We have had a **significant impact** on **accelerating melanoma research** and bringing **innovative treatments** to market, ultimately **improving patient outcomes** and **advancing the field of melanoma**

- **Rapid development of immunotherapies:** We played a crucial role in the successful delivery of clinical trials for immune checkpoint inhibitors, like pembrolizumab and nivolumab. Our efficient management and execution of these trials helped expedite the approval process, bringing these groundbreaking treatments to patients faster.
- **Targeted therapy innovations:** Our input was instrumental in the clinical development of targeted therapies for melanoma, such as BRAF inhibitors (vemurafenib and dabrafenib) and cell therapy treatments. Our expertise in trial design and patient recruitment accelerated the identification of effective treatments for patients with specific genetic mutations.
- **Combination therapy trials:** We facilitated the rapid testing and approval of combination therapies, such as BRAF inhibitors with MEK inhibitors (e.g., dabrafenib and trametinib). Our collaborative approach and robust trial management significantly reduced the time required to demonstrate the efficacy of these combinations.
- **Adjuvant therapy research:** Our involvement in adjuvant therapy trials for melanoma, including the use of nivolumab and pembrolizumab, helped accelerate the approval of these treatments for high-risk patients. Our efficient trial execution ensured timely data collection and analysis, leading to quicker regulatory decisions.
- **Expedited regulatory approvals:** Our expertise in navigating complex regulatory environments facilitated the accelerated approval of new melanoma therapies. Our strategic approach to trial design, data management and regulatory submissions ensured that promising treatments reached patients more quickly.

Our capabilities

Our **end-to-end solutions for melanoma 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 melanoma treatments**.

- **Study design and protocol development:** Expert consultation to create scientifically rigorous study designs and protocols aligned with regulatory expectations.
- **Patient recruitment and retention:** Advanced recruitment strategies that support timely enrollment, paired with patient-centric approaches that strengthen engagement and retention.
- **Site management and monitoring:** Comprehensive site management delivered by experienced clinical research associates who uphold protocol requirements and regulatory standards.
- **Data management and analysis:** State-of-the-art data management systems and an expert biostatistics team delivering reliable, high-quality results to support regulatory submissions.
- **Regulatory affairs and compliance:** Regulatory specialists who navigate complex global requirements, maintain compliance with local and international regulations, minimize delays, and facilitate approvals.
- **Safety and pharmacovigilance:** End-to-end safety monitoring and pharmacovigilance services, including adverse event reporting and proactive risk management.
- **Project management:** Dedicated project management teams with experience leading complex melanoma trials and driving seamless study execution.
- **Biomarker and genomic services:** Specialized biomarker and genomic capabilities that advance personalized medicine in melanoma, including biomarker identification, validation, and analysis to support targeted therapy development.
- **Post-trial services:** Comprehensive post-trial support, including data analysis, publication planning, and regulatory submissions for marketing approval to help transition from clinical development to commercialization.
- **Global site networks and relationships:** An extensive global network of preferred partner sites (e.g., PPD Select, EDOS site network) enabling rapid qualification and activation, supported by ongoing site capability development through our cell therapy site coach program and cell therapy site summits.

Our enrollment and retention services

Easing enrollment and increasing retention with patient-centric services

Enrollment solutions

Targeted recruitment strategies

- **Digital outreach:** Utilizing social media, online advertising and patient registries to reach potential participants.
- **Data-driven approaches:** Leveraging data analytics to identify and target populations most likely to meet trial criteria.

Site selection and optimization

- Selecting trial sites with a **proven track record** in melanoma research and access to a large patient population.
- Providing sites with tools and resources to **streamline the recruitment process.**

Patient advocacy partnerships

- **Collaborating** with melanoma patient advocacy groups and organizations to **raise awareness and encourage participation.**

Pre-screening tools

- Implementing pre-screening questionnaires and tools to **quickly identify eligible patients**, reducing the burden on trial sites and **speeding up the enrollment process**.

Community engagement

- **Engaging local communities** through outreach programs and events to **build trust and interest in clinical trials**.
- **Working with local health care providers** to identify and refer **eligible patients**.

Retention solutions

Patient-centric approach

- Ensuring that the trial design is **patient-friendly**, with flexible visit schedules and minimal disruption to daily life.
- Providing **clear and consistent communication** about trial procedures, expectations and benefits.

Support services

- Offering transportation assistance, lodging and other logistical support to **reduce barriers to participation**.
- Providing access to a **dedicated patient support team** to address concerns and provide assistance throughout the trial.

Engagement and communication

- Maintaining regular **communication with participants** through newsletters, updates and personalized messages.
- Using digital platforms and mobile apps to **keep participants engaged and informed**.

Incentives and compensation

- Offering appropriate **compensation for time and travel** to acknowledge the commitment of participants.
- Providing non-monetary incentives, such as **health check-ups and access to trial results**.

Patient education and empowerment

- **Educating participants** about the importance of their role in the trial and how their participation **contributes to advancing melanoma research**.
- **Empowering patients** with knowledge about their condition and the **potential impact of the trial on future treatments**.

Feedback mechanisms

- Implementing feedback systems to **gather participant input** and make necessary adjustments to **improve the trial experience**.
- Addressing any issues or concerns promptly to maintain **participant satisfaction and retention**.

By implementing comprehensive enrollment and retention strategies, we enable melanoma clinical trials to run efficiently, maintain strong participant engagement, and reduce dropout rates — ultimately supporting overall study success.