Accelerate your clinical trial with expertise in gastrointestinal cancers

Deep expertise across GI oncology

When developing clinical trials for gastrointestinal (GI) cancers, you need a clinical research partner with proven oncology experience, operational depth and scientific insight to help you navigate a complex, rapidly evolving treatment landscape.

The PPD™ clinical research business of Thermo Fisher brings extensive experience to GI cancer clinical trials across the development continuum, from early-phase trials to post-marketing studies. Over the past decade, our teams have enabled sponsors to address the unique challenges of GI oncology programs through informed trial design, efficient execution and access to a robust network of sites, investigators and specialized expertise in GI cancer biomarkers, treatments and emerging therapeutic approaches.

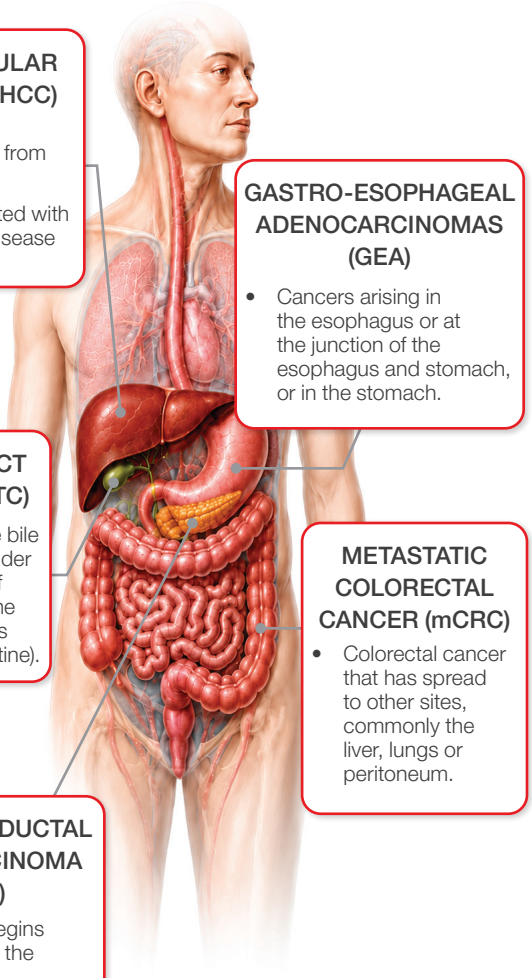
Our oncology subject matter experts, including specialists with deep GI oncology experience, support your program from study start-up through trial close-out—providing strategic input on protocol design, medical and scientific considerations, indication strategy, evolving standards of care, investigator and site training and comprehensive medical monitoring. This integrated approach protects patient safety, strengthens scientific data integrity and keeps your GI oncology program moving forward with confidence.

Disease background information

Gastrointestinal (GI) cancers—including hepatocellular carcinoma (HCC), pancreatic ductal adenocarcinoma (PDAC), metastatic colorectal cancer (mCRC), gastro-esophageal adenocarcinomas (GEA) and biliary tract cancers (BTC)—present significant global health and clinical development challenges.

GI CANCERS

Gastrointestinal cancers that impact millions of live worldwide



HEPATOCELLULAR CARCINOMA (HCC)

- Primary liver cancer arising from hepatocytes.
- Often associated with chronic liver disease and cirrhosis.

GASTRO-ESOPHAGEAL ADENOCARCINOMAS (GEA)

- Cancers arising in the esophagus or at the junction of the esophagus and stomach, or in the stomach.

BILIARY TRACT CANCERS (BTC)

- Cancers of the bile ducts, gallbladder and ampulla of Vater (where the bile duct meets the small intestine).

METASTATIC COLORECTAL CANCER (mCRC)

- Colorectal cancer that has spread to other sites, commonly the liver, lungs or peritoneum.

PANCREATIC DUCTAL ADENOCARCINOMA (PDAC)

- Cancer that begins in the ducts of the pancreas.
- Often diagnosed at an advanced stage.

For sponsors advancing new therapies in these indications, the landscape is increasingly complex.

- HCC represents the dominant share of primary liver cancers in the U.S.
- PDAC is often diagnosed at advanced stages and is associated with poor long-term survival.
- mCRC standards of care are evolving as biomarker-driven immunotherapies and targeted agents—including approaches for MSI-H/dMMR disease, BRAF V600E, HER2 and KRAS G12C—expand treatment options.

Across GI tumors, precision oncology is reshaping development strategies and creating new opportunities to deliver more personalized, effective therapies to patients.

At a time when speed, scientific rigor and operational precision are essential, we enable sponsors to navigate the complexity of GI cancer clinical development. With extensive global oncology expertise, a broad network of experienced research sites and professionals and patient-focused services designed to support recruitment and retention, we help you execute complex global trials with the insight, precision and support needed to advance your program.

By integrating therapeutic insight, operational excellence and a commitment to data integrity, we support efficient trial delivery and the development of innovative treatments for patients facing these formidable cancers.

Challenges with GI cancer clinical research

Developing therapies for HCC, PDAC, mCRC, GEA and BTC requires careful navigation of challenging disease biology, late-stage diagnosis and complex patient profiles.

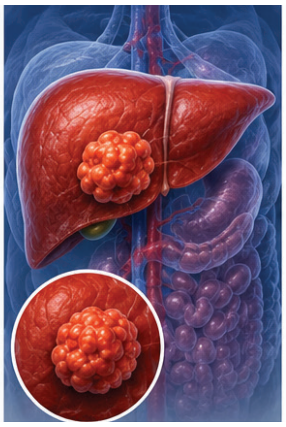
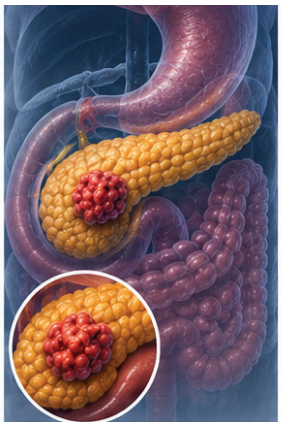
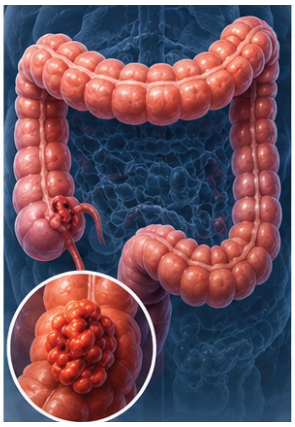
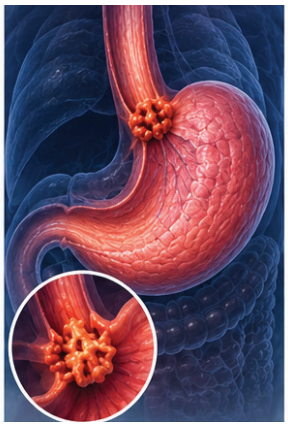
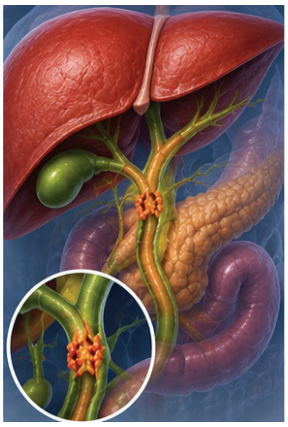
- In **HCC**, cirrhosis and other comorbidities may affect treatment selection and increase the risk of drug-drug interactions.
- In **PDAC**, late presentation and a dense desmoplastic stroma can limit curative options.
- For **BTC** and **GEA**, tumor location, anatomy and stage at diagnosis often complicate surgery and contribute to a high risk of recurrence.

As treatment options expand, sponsors need trial strategies that reflect both scientific opportunity and real-world clinical complexity. Broad next-generation sequencing (NGS) profiling is now recommended or commonly used in mCRC and is increasingly informing development strategies in GEA and BTC by helping identify actionable alterations. At the same time, PDAC and HCC remain areas of substantial unmet need, where innovative approaches and well-designed clinical trials are essential.

Multidisciplinary care, biomarker strategies, local standards of care, multidisciplinary site practices and the operational support are imperative to improving trial execution and advancing potential new options for patients.

GI CANCERS

Understanding and targeting cancers across the gastrointestinal tract and associated organs

HCC	PDAC	mCRC	GEA	BTC
				
Hepatocellular Carcinoma	**Pancreatic Ductal Adenocarcinoma**	**Metastatic Colorectal Cancer**	**Gastro-esophageal Adenocarcinomas**	**Biliary Tract Cancers**
Primary liver cancer arising from hepatocytes	Cancer of the pancreatic ducts	Colorectal cancer that has spread to other sites	Cancers arising in the esophagus or stomach	Cancers of the bile ducts, gallbladder and ampulla

Overview of our expertise

Built to help you navigate complex GI oncology trials

When you are advancing clinical trials in GI cancers, you need a partner that understands the operational, scientific and patient access challenges these studies present. Drug developers rely on us to support a broad range of GI cancer trials, from Phase I through Phase IV, including studies of novel therapies, combination regimens and biomarker-driven approaches.

Connect your program to experienced GI oncology sites and specialists

Access to the right sites, investigators and patient populations is critical. We support sponsors through a broad network that includes tertiary referral centers and sites experienced in biomarker testing, including:

- RAS
- BRAF
- MSI
- HER2
- RET
- NTRK
- TMB

Where relevant, we also consider opportunities to leverage networks of sites using Thermo Fisher Scientific's Oncomine solutions, where NGS may be part of standard care.

Our relationships with principal investigators who understand the evolving GI cancer treatment landscape support informed study planning, engaged site participation and execution aligned to the needs of each program.

Accelerate feasibility, startup and site selection

Selecting the right sites early can reduce delays and strengthen trial performance. We work with an experienced pool of sites, including Select Sites with master site agreements already in place, to move more efficiently toward key startup and enrollment milestones.

Our established site relationships also enable timely feedback on study design, patient population assumptions and operational considerations. This supports faster startup, more transparent communication and more engaged site participation throughout the trial.

Apply biomarker insight to strengthen trial strategy

As GI cancer treatment becomes increasingly biomarker-driven, sponsors need clinical trial strategies that reflect the latest scientific and diagnostic advances. We bring experience supporting GI oncology studies that incorporate relevant biomarkers and testing considerations into study design, site planning and execution.

We also work with patient advocacy groups (PAGs) and organizations to support awareness, education and earlier detection efforts in GI cancers, aligning clinical research with the broader needs of patients, providers and the oncology community.

Leading the way in GI cancer clinical trials

Our gastrointestinal cancer study experience in the past five years (2020 to 2025):

We have conducted:

59 gastrointestinal studies

Across **5,500+ sites** around the world

Involving **6,900+ patients**

Our GI cancer expertise ranges from early-phase studies to registrational trials. Sponsors turn to us for our experience supporting studies spanning a broad range of GI malignancies and trial designs, including HCC, PDAC, mCRC, GEA, BTC, large master protocols and rare biomarker-defined patient populations.

Gastrointestinal cancer study experience by phase and indication (2020 to 2025):

Phase/ Indication*	CRC	PDAC	HCC	BTC	GEA	Total
I	4	4	4	1	2	15
II	7	2	3	6	4	22
III	4	4	2	4	2	16
IV	2	2	3	0	5	12
Total	**17**	**12**	**12**	**11**	**13**	**65***

* Some studies have multiple indications

We manage and deliver studies across all phases and regions, with strong integration among patient advocacy groups. We also bring experience supporting programs that have achieved FDA Accelerated Approval, Orphan Drug Designation and Fast Track Designation.

Highlights of our GI cancer clinical trials expertise

Early-phase insight, built for momentum: Experience in first-in-human studies, Phase I dose escalation, MTD evaluation and RP2D identification to guide the path from early development toward regulatory advancement.

Patient advocacy connections: Collaboration with PAGs and support for GI cancer screening and early detection initiatives to keep patient needs central to development.

Biomarker-informed execution: Integration of biomarker testing into trial design to identify responsive patient subgroups, supported by collaboration with leading laboratories and institutions for high-quality analysis.

Precision medicine capabilities: Advanced oncology analytics and genomic profiling support to help inform smarter GI oncology trial planning and execution.

Oncomine™ genomic profiling: Access to Thermo Fisher Scientific's proprietary NGS platform to support biomarker-driven development strategies.

Feasibility powered by genomics: Genomic-driven feasibility assessments and biomarker-informed site strategy to help identify the right sites and patient populations.

Faster biomarker insight: Precision recruitment planning supported by rapid biomarker turnaround, with results available in approximately 24 hours across more than 500 genes.

Our approach to GI cancers clinical trials

Robust data collection and analysis

Leverage advanced technologies and proven methodologies to generate high-quality, compliant clinical data that supports confident decision-making.

Global reach and local expertise

Combine global scale with local market knowledge to optimize country selection, accelerate approvals and drive efficient patient recruitment across key regions.

Comprehensive feasibility studies and streamlined start-up approach

Target high-performing sites through data-driven feasibility and established relationships. Harmonized start-up processes accelerate country and site activation while maximizing enrollment potential.

Patient-centric trial design

Enhance recruitment, retention and patient experience through patient-friendly protocols, advocacy partnerships and decentralized trial solutions.

Keys to our success in GI cancer clinical trials

Start-up and enrollment strategy success driven by:

- Selection of the right regions and countries
- Engagement of high-performing sites with proven oncology trial experience
- Strategic use of established investigator relationships and key partnerships
- Acceleration of site activation through preferred site networks, reducing start-up timelines by up to 30 days

Our recommendation is to design protocols with pragmatic, inclusive eligibility criteria that reflect real-world patient populations and appeal to both investigators and patients. For U.S. studies, a balanced mix of academic centers and experienced community oncology sites is critical to maximize enrollment potential.

Data-driven feasibility and site selection

We tailor study strategies based on:

- Investigator interest and engagement
- Competitive trial landscape
- Regulatory requirements
- Local standards of care
- Patient availability and safety considerations
- Leveraging real-world evidence and market intelligence enables informed country and site selection, particularly in regions with varying standards of care and biomarker testing practices

Proven operational excellence

Our global oncology teams combine therapeutic expertise, operational excellence and innovative solutions to support successful study delivery worldwide.

Recent successes include:

- Accelerated enrollment delivery in complex oncology and rare disease programs
- Enrollment completion significantly ahead of sponsor projections through proactive site support, patient identification strategies and focused study management
- Global execution capabilities spanning North America, Europe, Asia-Pacific, Latin America, the Middle East and Africa

From study design through database lock, we deliver customized solutions that proactively address challenges and accelerate development timelines.

End-to-end solutions to successfully deliver your clinical trial

- A global network of >2,000 experienced principal investigators, with indication-specific expertise
- Optimized, data-driven country and trial site selection
- Deep understanding of key protocol components impacting enrollment
- Clinical and regulatory strategy consulting
- Relationships with key opinion leaders
- Global strategic partnerships with top performing sites
- Characterization, endpoint determination and patient recruitment expertise
- Site activation, enrollment and retention strategy development
- Strategic development consulting expertise in core disciplines (CMC, toxicology, pharmacology)
- Data management and ophthalmology expertise in biostatistics, quality and regulatory expertise
- Support services for optimizing access and minimizing patient burden

Experience to help you meet your diversity goals

Recommended U.S. cancer centers' strategy to support diversity goals:

To support achievement of study-specific diversity goals in GI cancers, we recommend prioritizing U.S. cancer centers and hospital networks with demonstrated access to racially and ethnically diverse patient populations and established infrastructure to support inclusive enrollment.

Recommended site attributes include:

- Proven experience recruiting racial and ethnic minority participants, with historical minority accrual of approximately 10–50%
- Catchment areas where minority populations represent ≥10% of the total patient population
- Established relationships with key hospitals and cancer centers serving diverse communities
- Bilingual providers and site staff that reflect the communities they serve to support patient communication and engagement
- Existing diversity enrollment programs and community outreach initiatives
- Cultural competency training to support equitable, patient-centered trial participation

Easing enrollment and increasing retention with patient-centric services

We recognize how burdensome clinical trials in GI cancers can be for patients and their caregivers. Our host of supportive concierge services reduces the burden for both sites and patients and makes it easier for patients to participate in the trials and stay longer by offering:

- **Telemedicine & Home Health care Services**
- **Digital & Decentralized Protocols**
- **Transportation Coordination & Verification**
- **eCOA/ePRO**
- **Flexible Reimbursement Options**
- **Wearable & Mobile Pagers**

These services produce timely and high-quality data for our sponsors while saving patients time and cost. Our patient-centric approach has led to more than 90% patient retention over five years for a recent long-term follow-up trial.

Our extensive experience and expertise in GI cancers clinical trials make us a trusted partner for sponsors seeking to advance their therapies.

With a comprehensive approach, from feasibility to execution, we ensure that trials are conducted efficiently, ethically and with a focus on patient outcomes.

Partner with us to leverage our unmatched expertise and drive the success of your clinical trials.

Let's accelerate your GI clinical trials together.

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