



Gastroenterology

**Accelerate your clinical trial with our
gastrointestinal experience**

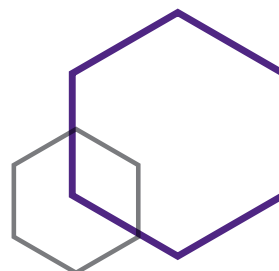


Advancing gastrointestinal research: Proven expertise and established GI networks for delivery

Gastrointestinal (GI) research is essential for improving the diagnosis, treatment and long-term management of diseases that affect millions of people worldwide.

Gastrointestinal studies can face specific challenges because of the invasive nature of investigation with endoscopies and colonoscopies, fluctuating disease symptoms and microbiome complexity. GI diseases are biologically heterogeneous and require careful selection in endpoint selection, biomarker exploration, identification and treatment response prediction and understanding factors affecting placebo response. There is also strong focus on developing more patient-centered and real-world approaches to care through digital health technologies, remote monitoring and personalised treatment strategies.

To maximize success sponsors often turn to an experienced contract research organization (CRO) service provider with established partnerships, networks and an understanding of the above factors that to help navigate the inherent complexities and increase the likelihood of successful outcomes.



Sponsors partner with the PPD clinical research business of Thermo Fisher Scientific to bring the following advantages:

Therapeutic experience

- In the last five years we have conducted **110** GI clinical studies globally.
- Our operational subject matter experts span a broad range of GI diseases.
- Our expert team includes a global group of seven board certified gastroenterologists.
- We have clinical science liaison staff who meet GI teams at sites to maximize scientific discussions and study delivery.
- We have an integrated endpoint business unit which brings together advanced analytics and endpoint expertise to generate richer insights.
- In the last five years we conducted studies that led to the approval of the following GI products:
 - FDA approval for the first potassium-competitive acid blocker for the treatment of erosive Gastroesophageal Reflux Disease (GERD) and relief of heartburn associated with Erosive GERD in adults (Vonoprazan®)
 - FDA/EU approval of treatment for Primary Biliary Cholangitis (PBC) (Livdelzi®)
 - We conducted Ulcerative colitis (UC) and Crohn's disease (CD) studies/analyses resulting in FDA/EU approvals for two new treatments in the United States and Europe (Zymfentra® and Zeposia®)

Investigational sites network

- Our global site network of GI sites enables us to place studies for successful eligibility and recruitment of patients and delivery of studies.
- We have **126** GI networks (commercial and academic/hospitals) and 64 partners which we work with across **22** countries.
- We build strong relationships with sites and understand their capabilities which are mapped and analysed in our databases.
- We have access to over **7,900** GI sites to select to run studies.
- Our PPD™ Select (PPDS) sites are specific sites which we have built a close relationship with. They are sites that generate high-quality data, have access to a broad patient population and have PIs that are leaders in their field.

Patient-centric solutions

- We offer decentralized solutions to enable home nursing and at-home administrations, enabling a greater reach and inclusion of patients.
- We have strong links with community networks and patient advisory groups to increase patient awareness and engagement of active trials.
- We advise on optimization of trial design to remove barriers to patient participation and reduce protocol burden which can support recruitment of diverse cohorts.



Integrated clinical trial services: Expert advice and support at every stage of the process

We offer full-service capabilities spanning from early phase development through all phases of clinical development to post approval, and we have supported the development of 110 GI trials in the last five years. We also offer strategic consultancy at all stages of clinical development and study delivery.

Our experience includes working with many types of customers, including biopharmaceutical and biotechnology organizations, academic institutions and consultancies, with a flexible working model that adapts to the needs of your business.

Our gastrointestinal experience over the past five years



110
GI studies



7,900
Investigators



19,300+
Patients



23
Non-interventional studies

Sponsors benefit from our wide-ranging gastroenterology experience, spanning all clinical trial phases and broad spectrum of indications.

As a leader in key gastroenterology indications, we can enable sponsors to implement successful strategies when conducting GI trials. We have dedicated professional teams, including a global team of gastroenterologists with deep GI experience, running successful studies.

Our experience in key indications over the last five years encompasses:

Indication	Number of protocols	Number of sites	Number of patients
Ulcerative Colitis	22	2,476	3,650
Crohn's Disease	20	1,869	4,400
Primary Biliary Cholangitis	10	710	1,172
Gastroesophageal Reflux Disease	12	573	3,212
Eosinophilic Esophagitis (EoE)	6	444	1,056
Irritable Bowel Syndrome	5	254	1,273
Metabolic dysfunction-associated steatohepatitis (MASH)	4	117	125
Alpha 1-Antitrypsin Deficiency	3	142	158
Inflammatory Bowel Disease (UC&CD)	4	491	853
Celiac Disease	3	58	118
Short Bowel Syndrome	3	49	92
Primary Sclerosing Cholangitis	2	64	30
Nausea	2	5	212
H. Pylori Infection	2	216	2,068
Other and rare indications	12	446	949
Total	110	7,914	19,368

What our experience means for you:

- Rapid start-up through defined point of contacts and streamlined processes.
- Offer a range of decentralized, digital and AI solutions to make trial participation easier and more inclusive for patients, enhancing patient recruitment and retention.
- Strong experience with central endoscopy services ensuring efficiencies and timeliness of readout data.
- Excellence in-study management and vendors ensuring study efficiencies.

Keep your gastrointestinal development on track with our experienced team

Dedicated gastrointestinal experience

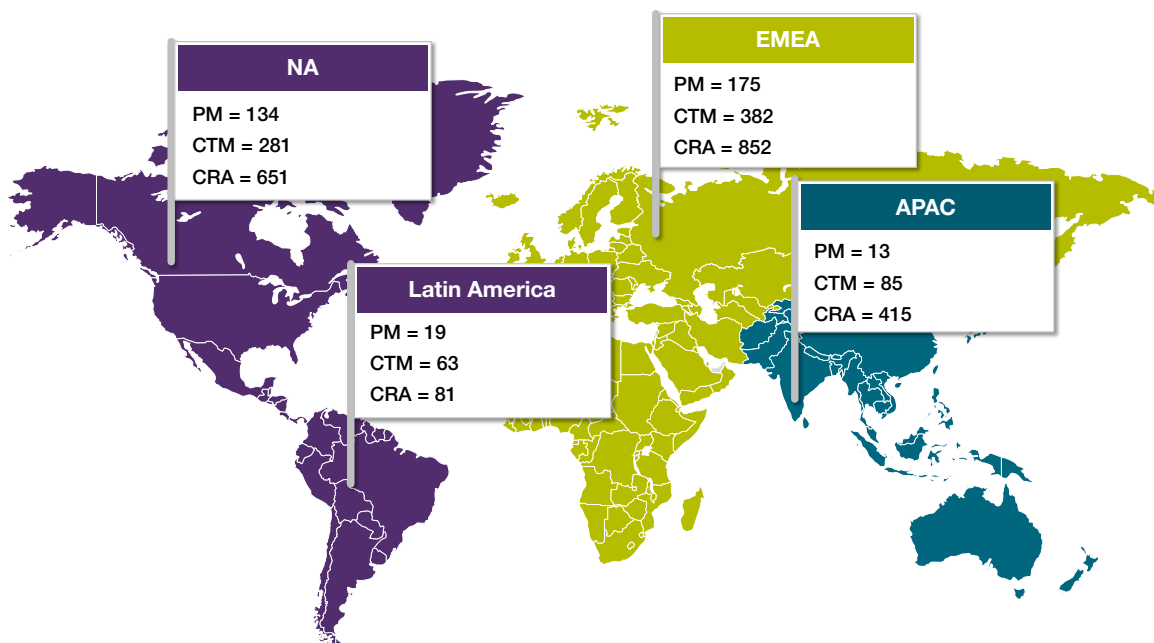
Our global gastrointestinal team is comprised of **3,151** experienced project leads, clinical trial managers and clinical research associates. These professionals include a team of more than **341** project management experts serving as your key point of contact and responsible for overall project delivery and quality. We also provide medical monitoring by board-certified physicians, as well as dedicated data management and statistic team members with far-reaching gastrointestinal study experience. With a retention rate of **95** percent over the past three years, our experts are well positioned to work together to execute successful gastrointestinal trials.

Our Inflammatory Bowel Disease (IBD) University learning program is designed to build knowledge and confidence in monitoring IBD clinical trials, with a focus on ulcerative colitis and Crohn's Disease. The program provides practical training, promotes discussion around study-specific challenges, and supports networking among study teams.

Key success factors:

- Understand protocol-specific requirements
- Proactive in site support
- Focus on endpoint quality and patient compliance
- Identify operational risks early
- Partner effectively with study sites and vendors

With over 100 people training with two cohorts per year, we are confident in our clinical team to deliver with excellence.



A partnership with gastrointestinal sites

In addition, we have developed a liver academy to strengthen our knowledge base in this therapeutic area and to better meet the needs of our clients. This training was designed to provide our team with the knowledge and skills needed to operate effectively in an emerging and specialized therapeutic field. The curriculum equips our team to understand and manage the unique requirements of liver clinical trials with confidence, strengthening our ability to lead and support liver trials that are compliant, efficient and impactful.

The liver academy includes a general introduction to liver anatomy and physiology and considerations for monitoring liver disease studies. It also includes courses that explore the disease state and methods used to diagnose Primary Biliary Cirrhosis, Primary Sclerosing Cholangitis, and Metabolic Dysfunction-associated steatohepatitis (MASH), building a solid foundation for understanding the research being conducted for these diseases.



Our trial feasibility services

Our trial feasibility team is dedicated to helping sponsors establish a strong foundation for successful clinical development. By combining strategic expertise, comprehensive data analysis and global operational capabilities, we deliver tailored feasibility solutions that support informed decision-making from the outset.

Our feasibility strategists leverage insights from diverse data sources to develop customized feasibility strategies aligned with your study objectives, therapeutic area and operational requirements. Every engagement is designed to address your specific needs while keeping the end goal—efficient study execution and successful site activation—in focus.

Our experienced feasibility managers translate strategy into execution by leading targeted site outreach and site identification activities. Working in close collaboration with our global network of local representatives, they identify and engage high-performing investigational sites that are best positioned to meet your study requirements, helping to accelerate enrolment and optimize trial performance.

As a leading global CRO service provider, we combine extensive therapeutic expertise, broad geographic reach and deep operational experience to deliver feasibility solutions that reduce risk, improve site selection and support the successful delivery of your clinical trials.

Rare GI feasibility case study

We recently conducted a complex feasibility study in a rare GI condition for a mid-sized biotech sponsor’s Phase III trial. The outreach spread to 22 countries in three regions. The study needed principal investigators and sites with multiple specialties, and the complexity of patient care further reduced the pool of eligible sites. By targeting large GI centers capable of complex treatment and adding sponsor-assisted outreach to improve engagement, the feasibility was successfully completed.

As a result, 54 surveys were completed by potential study sites. The geographic spread helped identify viable site distribution, and sponsor outreach improved the response rate. This highlights the value of our extensive experience and demonstrates that, for rare GI indications, feasibility assessments must prioritize center expertise, geographic access, multidisciplinary care and proactive engagement, not just patient volume.

Rare GI example sites:

Country	Institution	PPD Rare GI studies	Total PPD experience
Germany	Charité - Universitätsmedizin Berlin	3	239
United States	Mayo Clinic - PPDS	3	162
Spain	Hospital Universitario Virgen del Rocio - PPDS	3	190
Belgium	UZ Leuven - PPDS	2	40
Italy	Fondazione Policlinico Universitario A Gemelli - Rome - PPDS	1	153

IBD case study

We conducted feasibility for a Phase II IBD trial for a large pharma client and:

- Successfully navigated mid-feasibility protocol changes and country-specific enrollment caps, helping maintain momentum despite evolving study requirements.
- Reached approximately 1,500 ulcerative colitis sites across 34 countries and all four regions, providing broad access to a diverse global investigator network.
- Activated approximately 190 sites, demonstrating the ability to translate large-scale outreach into meaningful study readiness.
- Delivered a coordinated multinational feasibility strategy, helping support informed country and site selection for a complex global program.



The PPD Select Partnership Program

Purpose and value:

The PPD™ Select Partnership Program is designed to enhance collaboration with strategically chosen sites, optimizing study delivery and performance across all stages of the study life cycle. By fostering strong partnerships, the program aims to streamline site identification and selection, ensuring efficient and effective study execution.

Key outcomes:

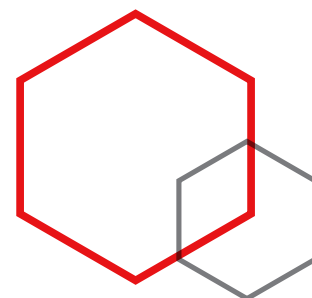
- Improved project delivery timelines and differentiated performance.
- Enhanced site engagement and retention.
- Increased operational efficiency and reduced study costs.
- Strengthened our position as the 'CRO of Choice' through trusted and differentiated site relationships and study outcomes.

Practical implications for relationship managers include the ability to:

- Proactively engage with our sites to build and maintain strong partnerships.
- Utilize program resources to support site identification, selection and performance monitoring.
- Collaborate closely with our team to refine processes and leverage insights for optimal study delivery.

Why this matters now:

In the current competitive landscape, the ability to deliver studies efficiently and effectively is crucial. The PPD Select Partnership Program provides a strategic advantage by ensuring that we work with the best sites, thereby enhancing our overall performance and client satisfaction. Matching the best sites with the most relevant studies maximizes access to patients, further improving study outcomes. Immediate engagement and alignment with this program are essential to maximize its impact and secure our leadership position in the industry.





Trialmed™ provides comprehensive clinical pharmacology services across all phases of clinical development. With more than **250 global study sites** and access to a database with **20 million patients**, Trialmed ensures flexible locations for optimal patient engagement. Their network design offers comprehensive solutions for trial design, patient recruitment, data management, and regulatory compliance, simplifying the study conduct process for pharmaceutical companies and research institutions. Trialmed's integrated global clinical site network offers robust solutions for early development service needs, connecting businesses with the resources necessary for successful clinical trials. Additionally, their Home Trial Services (HTS) solution supports decentralized trial enrollment, making clinical trials more accessible and removes patient burden.

Trialmed creates holistic experiences that put the patient first through welcoming clinics, user-friendly digital technology, and a relentless focus on total quality delivery. With a patient-first approach, Trialmed is the clinical research destination of choice for patients and healthy volunteers.

With **extensive access to patients in multiple geographies**, Trialmed ensures reliable enrollment outcomes. Trialmed offers extensive **early phase solutions** with a dedicated team, and a large suite of offerings.



Flexible clinical trial solutions scale to the sponsor's needs and budget, offering a best-in-class site network from **Phase I to Phase IV**.

Home Trial Services offer the ultimate in-patient flexibility – conducting clinical trial visits where the patient prefers, such as the patient's home, office, or school.

Trialmed has extensive experience in GI clinical trials, having randomized 2,863 patients across various indications and delivered more than 69 Phase I-IV trials. They possess deep expertise in engaging patients with GI conditions in their preferred ways, supported by a robust proprietary database that provides insights on patients most likely to randomize. This data base includes many households reporting GI conditions.

Key advantages of working with Trialmed include:

- Proven recruitment tactics focused on finding and enrolling challenging trial cohorts.
- Access to a large, pre-screened patient population, enhancing the efficiency of patient recruitment.
- Expert clinical staff and experienced research site teams, ensuring standardized SOPs, project management, and high-quality trial execution.
- Support for over 80 sites, providing extensive reach and flexibility for clinical trials

Patient first digital solutions in gastrointestinal studies

Our Patient First Digital solutions (PFDS) integrate cutting-edge technology, digital partnerships and data-driven strategies to accelerate recruitment while making research more accessible, inclusive and efficient for patients. We break down traditional barriers and infuse innovation to expedite drug development and trial delivery for our clients.

Our patient registry offers opportunity to contact patients directly about research opportunities by direct email, text or phone calls.

HealthUnlocked™ is an online patient community and social platform that connects people with the same condition and can signpost them to medical research opportunities. It provides access to target audiences and awareness, in addition to providing an authentic voice of the patient via social listening giving insights as to what matters most to patients.



98K

Patients screened globally for GI studies

22K

Patients randomized globally for GI studies

66K+

HealthUnlocked members in our GI online community

2M+

People noting a GI related condition in our Patients Registry Registries

We also partner with specialist approved partners who utilize AI for automated review of standard of care endoscopies and various AI techniques for the identification of eligible patients against study criteria. Sites then contact the pre-selected patients for follow up.

Iterative Health™ is an example of an approved partner which works with us. Working as an extension of our team, we combine specialized gastrointestinal expertise, AI-enabled technology, proven processes, and advanced data visibility to optimize patient identification and screening, provide real-time insights into study performance, and support informed decision-making throughout the trial. This collaborative approach streamlines execution, improve enrolment efficiency, and reduce unnecessary screen failures.

Patient centricity forms an important part of our approach where we put the patient's voice and trial experience at the forefront of our considerations. Gastrointestinal trials can benefit from the utilization of digital approaches to alleviate the burden of patients needing to visit clinics every time.



Experience includes:

21

Overall studies conducted with a Digital Implementation manager (DIM) demonstrating extensive experience and expertise

40+

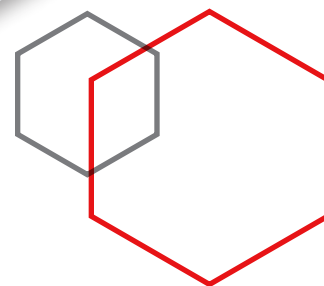
Patients randomized globally for GI studies

14

Studies supported by a licence and translation manager which ensures a consistent Clinical Outcome Assessment (COA) licensing and translation management oversight. We work seamlessly with COA copyright holders, authors and distributors and have an in-depth knowledge of linguistic validation methodologies

31

Studies with a digital and centralized solution on (eConsent, eCOA, televisits, wearables, direct to/from patient shipments, home health care and Patient Navigator)



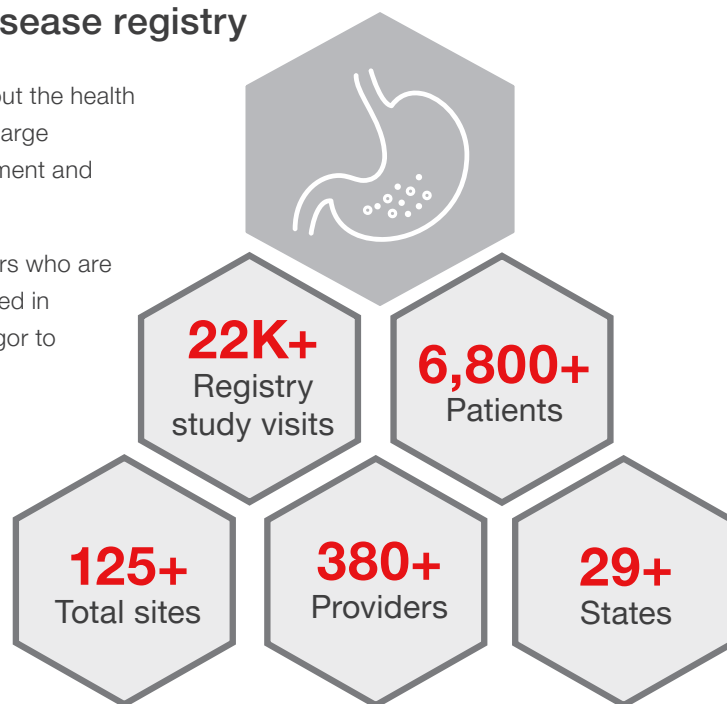
Accelerate IBD therapy development with PPD CorEvitas Dermatology Registries

PPD™ CorEvitas™ Inflammatory Bowel Disease registry

Our independent CorEvitas clinical registries track information about the health status of US patients and the care they receive, bringing together large regulatory-grade proprietary data sets to analyze patterns in treatment and outcomes, informing best practices and treatment decisions.

Developed and maintained under the guidance of scientific advisors who are preeminent experts on IBD, the CorEvitas IBD registry was launched in 2017 and features exceptional data completeness and scientific rigor to answer critical research questions in gastrointestinal conditions, such as those related to:

- Natural history and unmet need
- Comparative effectiveness
- Correlation of clinical outcomes with patient-reported outcomes (PROs)
- Patterns of care and reasons for treatment start/stop/switch
- Post-approval safety and effectiveness



Examples of the clinical and patient-reported data collected:

- Disease location and phenotype
- IBD-related extraintestinal manifestations
- Harvey-Bradshaw Index (Crohn's disease)
- Simple Clinical Colitis Activity Index (SCCAI) (Ulcerative colitis)
- Mayo Severity Index
- PROMIS – Anxiety, depression, fatigue, sleep disturbance, pain interference
- Work Productivity and Activity Impairment (WPAI)





Our experience in GI pediatric and rare diseases

Our teams have experience in a range of pediatric studies and rare diseases.

Over the past five years, we have successfully supported **nine pediatric gastroenterology studies**, providing sponsors with specialized expertise across the unique operational, regulatory, and patient-centric challenges of pediatric GI clinical research.

Our Pediatric Investigator Network (PIN) is a global network of 24 pediatric Centers of Excellence established to accelerate and optimize the development of therapies for pediatric populations. The network provides access to pediatric disease experts and research-experienced sites while supporting rapid feasibility assessments and protocol development for pediatric clinical trials.

Our pediatric research solutions team provides a meaningful advantage for pediatric GI studies. Our team brings deep expertise in pediatric protocol strategy, feasibility, enrolment planning and investigator engagement. The pediatric research solutions team leverages long-standing relationships across children's hospitals and pediatric research organizations to support targeted site identification, investigator engagement and enrollment planning. This provides a deeper understanding of site capabilities, patient access, competing studies and operational readiness before startup activities begin.

Our longstanding relationships with a global network of pediatric gastroenterology sites and investigators enable targeted feasibility assessments, optimized site selection, and efficient study startup.

Through repeated collaboration, we maintain detailed insight into site capabilities, patient access, and enrollment performance, placing studies with sites best positioned for successful execution. We combine this network strength with dedicated study teams experienced in both pediatric and gastrointestinal research.

Our teams provide proactive oversight of critical study milestones, complex eligibility assessments, endoscopic procedures, laboratory testing, and protocol-specific endpoints to support consistent protocol adherence and high-quality data collection throughout the study lifecycle.

Our established partnerships with leading pediatric gastroenterology key opinion leaders (KOLs) and patient advocacy organizations, including the Crohn's & Colitis Foundation, Fatty Liver Alliance, and PBC Foundation, provide valuable insights into evolving standards of care, patient needs, protocol design, and recruitment strategies. These collaborations strengthen patient outreach efforts and support access to established patient communities and referral networks.

By combining therapeutic expertise, established site and investigator relationships, and operational excellence, we enable sponsors to efficiently navigate the complexities of pediatric GI development and advance innovative therapies for children with unmet medical needs.

Thermo Fisher Scientific – providing a wide range of services and products

In addition to providing clinical research services, Thermo Fisher Scientific manufactures assays and analytical equipment that is used by clinicians and researchers managing gastrointestinal disease.

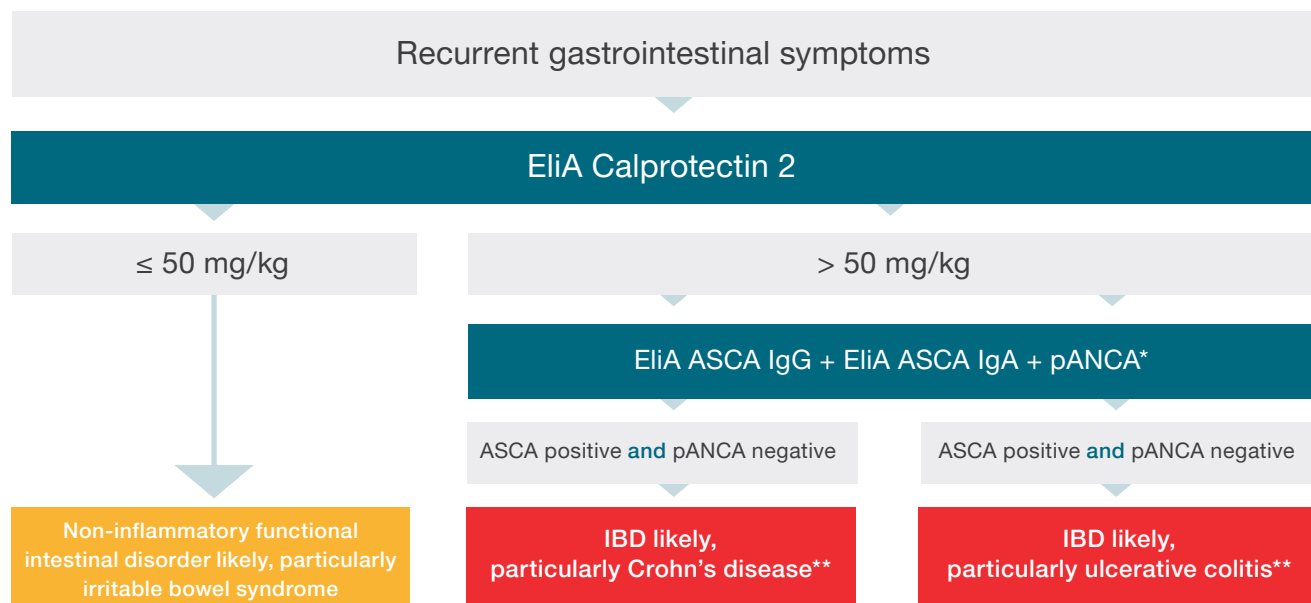
For example, Thermo Fisher has developed an EliA™ portfolio to support the identification and differentiation of inflammatory bowel disease (IBD) to functional disorders.

IBD is characterized by destructive inflammation of the intestinal tract with Ulcerative Colitis and Crohn's Disease as the most common disorders. Both diseases are life-long conditions with periods of remission and relapse. Fecal calprotectin is a biomarker of intestinal inflammation, and its presence and identification can help distinguish between non-inflammatory bowel disorders (e.g IBS) and IBD.

The EliA™ IBD portfolio, comprising the EliA Calprotectin 2 and the EliA™ ASCA IgA and IgG tests (ASCA: anti-Saccharomyces cerevisiae antibodies), supports the identification and the differentiation of IBD. The EliA™ gastrointestinal portfolio* enables you to help rule in or rule out IBD (and subsequently differentiate between Crohn's disease and ulcerative colitis), IBS, celiac disease, non-celiac gluten sensitivity, and wheat allergy operator.

*EliA Calprotectin 2, EliA ASCA IgA and IgG, EliATM Celikey IgA and IgG, EliATM GliadinDP IgA and IgG tests, ImmunoCAP™ Wheat allergen, f4

Inflammatory bowel disease



*pANCA: antibodies against granulocytes with unknown target antigen ** clarification or confirmation by colonoscopy

Selected relevant guidelines for this test algorithm

- "ECCO-ESGAR Guideline for Diagnostic Assessment in IBD Part 1: Initial diagnosis, monitoring of known IBD, detection of complications", Maaser et al. 2019⁵²
- "World Gastroenterology Organisation Global Guidelines Inflammatory Bowel Disease: Update August 2015", Bernstein et al. 2016⁵³

AcceleratorTM Drug Development

360° CDMO and CRO solutions

The manufacturing process in gastroenterology drug development is fundamental to the success of the product. It ensures the final product meets the necessary regulatory standards and provides the required evidence in terms of quality, safety and efficacy.

The PPDTM clinical research business of Thermo Fisher Scientific is a leading global provider of a full suite of innovative CDMO (contract development manufacturing organization) and CRO services as core offerings.

Partner with us at any point in your unique drug development journey to accelerate your goal of getting treatments to patients faster, and benefit from our gastroenterology expertise in both CRO and CDMO solutions.

Gain an advantage by partnering with a CRO that also has CDMO expertise with drug manufacturing process.

Thermo Fisher Scientific is a leading global provider of a full suite of innovative CDMO (contract development manufacturing organization) and CRO services as core offerings. Partner with Thermo Fisher Scientific at any point in your unique drug development journey to accelerate your goal of getting treatments to patients faster, and benefit from our dermatology expertise in both CRO and CDMO solutions.

We deliver:

Speed – Work with one partner, instead of multiple vendors, to proactively mitigate risks and eliminate timeline gaps and regulatory challenges.

Operational flexibility – Meet your unique program development and research requirements, both locally and globally, with our innovative solutions and scalable manufacturing and clinical research solutions.

Collaborative partnership – Get the integrated expertise you need across all phases of your drug development journey.

More than 120 biotech and biopharma companies are currently accelerating their time to market by partnering with Thermo Fisher Scientific across our CDMO and CRO services on more than 350 protocols.

Accelerator drug development



Partner with us starting at **any point**, in **any phase**

Preclinical, IND, Phase I

Benefits:

- De-risk early-phase development
- Gain speed to IND and Phase I trials
- Scientific and regulatory expertise

Phase II-III, NDA

Benefits:

- Speed to market
- Cost efficiency
- Streamlined supply chain and labs
- Patient recruitment and retention
- Global reach and expertise

Commercialization and post-approval studies

Benefits:

- Maximize an asset's market potential
- Manufacturing capacity
- Post-approval studies
- Real-world data (RWD) and real-world evidence (RWE)

Accelerating your unique drug development journey with innovative 360° CDMO and CRO solutions, supporting your aspiration to get treatments to patients faster

Every drug development journey is unique. That is why you can partner with Thermo Fisher Scientific at any point, in any phase of your drug development and gain benefits by using combinations of our global expert CDMO, CRO, clinical supplies, labs, regulatory and consulting services.

If you are in pre-clinical development, we can provide you with speed to Investigational New Drug (IND) by manufacturing your investigational medical product, using our GMP labs for testing, and leveraging our expert chemistry, manufacturing and controls (CMC) and regulatory consulting services for your IND application and Phase I trial planning.

We can provide benefits for Phase II and III trials if you partner with us for your clinical research, clinical trial supplies, and central lab services by using our integrated trial supply and demand forecasting systems.

Your greatest time savings and your highest return on investment can be achieved by starting your drug development journey with us. We understand that every customer has different immediate needs and business objectives. We have a comprehensive array of services that can meet your needs including a combination of our drug substance and drug product services, our clinical research services, and our GMP and central lab services.

Regardless of where you are in your journey – we can enable you to achieve the ultimate goal of getting your treatments to patients, faster.

Let's connect

Contact us today at <https://www.ppd.com/therapeutic-expertise/gastroenterology/> and discover how we can support your journey to groundbreaking gastrointestinal drug development.



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