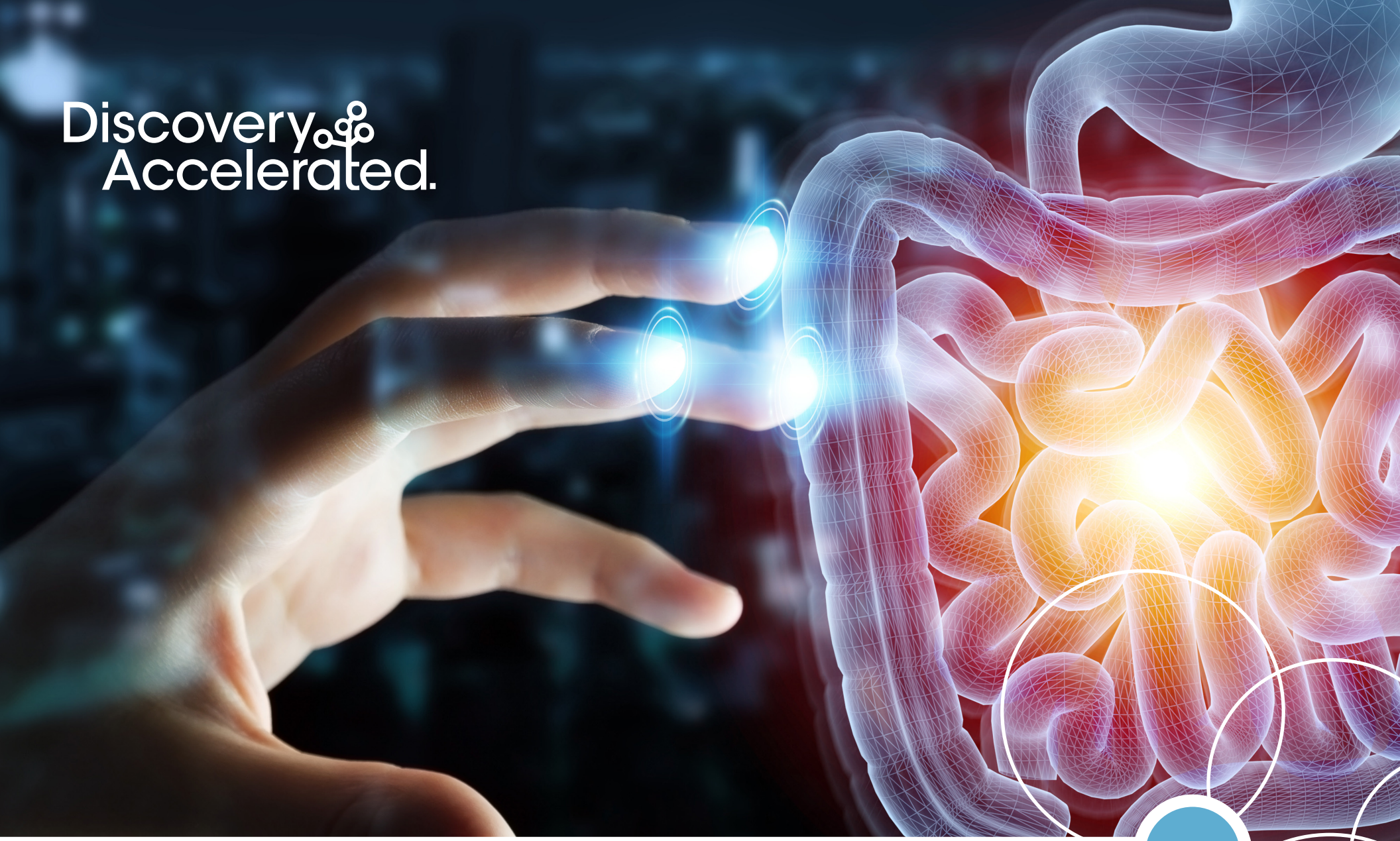


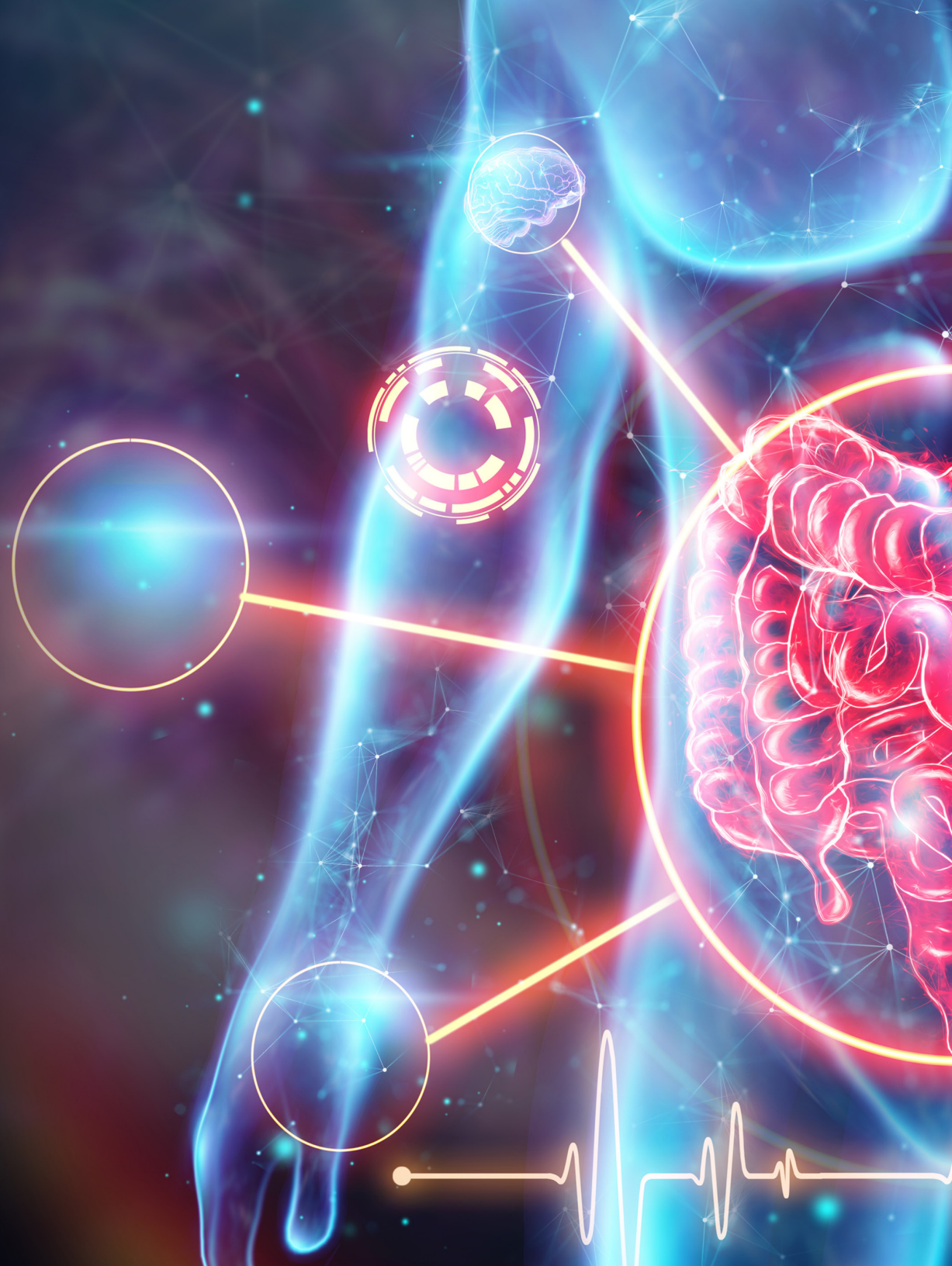
GI Medical Imaging Solutions

Expertise, services, and technology to ensure the quality of your outcome measure in GI research.

alimentiv™

Discovery Accelerated.

End-to-end services for endoscopy, histopathology, and MR Imaging. Endpoint data you can trust.



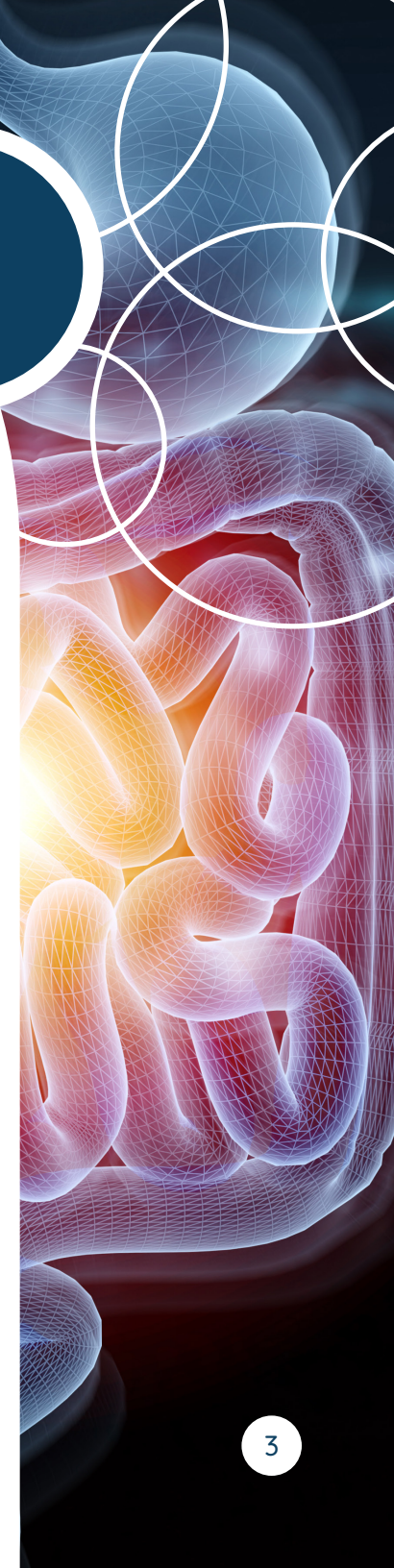


Table of Contents

Leading With Science, Alimentiv is a CRO with deep expertise in GI-related research.

Alimentiv's comprehensive portfolio of Gastroenterology (GI) focused Imaging Solutions are used globally in image management and full-service projects. Whether you are in the planning phase or need assistance with an ongoing project, our service-oriented team can provide you with the tools, services, and expertise needed to accelerate your project.

Why Choose Alimentiv For Your GI Medical Imaging

- Alimentiv is the leader in the development of GI medical imaging solutions. Since 2007 our expert team has been offering central image management of endoscopy, histopathology, and magnetic resonance (MR) services.
- Strong knowledge and relationship with over 4,000 GI sites worldwide built through a myriad of image management and full-service projects. These sites are familiar with our imaging solutions resulting in quick startup timelines and smooth processes through trial conduct.
- Streamlined communication and a practical approach to running projects adapted to meet the unique needs of your project. Alimentiv has dedicated project teams for Medical Imaging.
- A commitment to strategic and innovative thinking in partnership with the sponsor. With our team of recognized medical and imaging experts, we provide support for your clinical trial.
- 21 CFR part 11 compliant reading solutions for endoscopy and histopathology central reading developed by Alimentiv. Alimentiv is currently developing a 21 CFR part 11 compliant reading solution for MR.
- Thorough onboarding and study-specific training of our Central Readers to minimize Intra and inter-reader variability. Our Central Readers are expert gastroenterologists, pathologists, and radiologists.
- Ability to act as a single source for image services, including endoscopy, histopathology, and MR.
- Collaboration with our sister company AcelaBio, a fully accredited commercial state-of-the-art research laboratory delivering end-to-end histopathology and precision medicine services for GI global clinical trials.

Alimentiv also offers a full-service model where our scientific, operational and regulatory leadership can help your team accelerate drug development. We uniquely understand the challenges of today's landscape and are committed to offering services that fit your needs and stage of development. We can assist your team with operational challenges from limited resources to a depth of experience in a particular area. Our full-service model includes:

- Comprehensive phase I–IV clinical trial services for GI-related research that include unique planning, start-up, initiation, oversight, close-out, and reporting for all phases.
- Risk-Based Quality Management (RBQM) approach to site activities, supported by a Project Management and Monitoring team experienced in GI.
- Precision Medicine lab services and scientific expertise of key opinion leaders.

About Us

Alimentiv is the leading Medical Imaging partner for your gastroenterology clinical trials

Alimentiv is a gastrointestinal (GI)-focused specialty Contract Research Organization (CRO) that provides a broad range of clinical research services to pharmaceutical and biotechnology companies, Clinical Research Organizations, and academic investigators.

Our goal is to improve the lives of patients, their families, and their caregivers by supporting the development of novel treatments. Alimentiv helps companies design and implement GI trials, imaging solutions, clinical pharmacology, real-world evidence, and precision medicines services in an integrated, expert, and evidence-based way while meeting complex operational needs and regulatory standards.

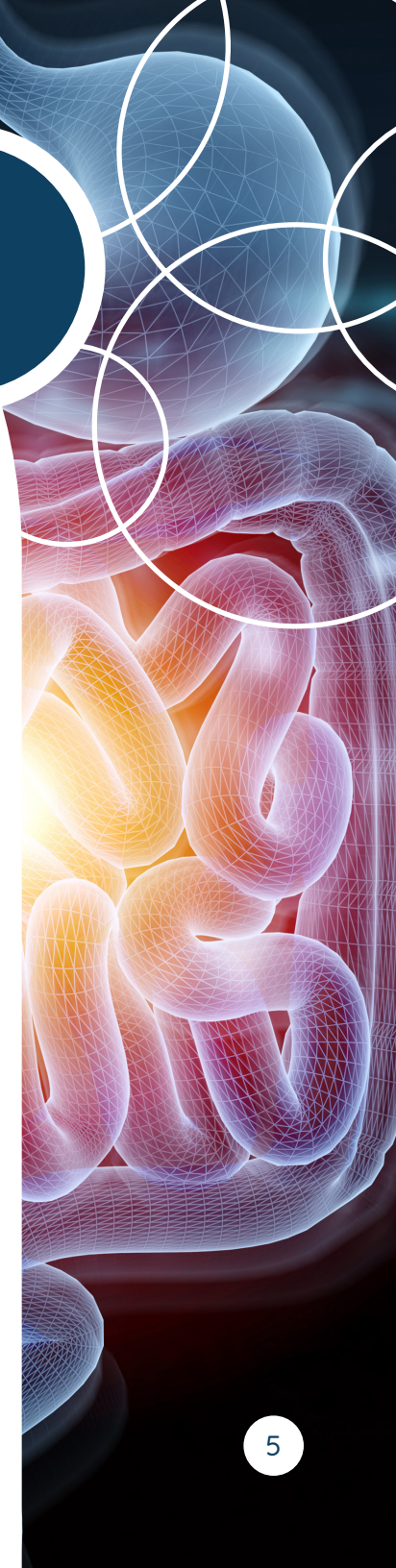
Our scientific leadership, combined with our medical and operational expertise, is what differentiates us from the competition. Profits generated by Alimentiv are used to fund important academic research initiatives that are consistent with our mission to transform human health. We leverage this research to develop novel and improved existing outcome measures, which can be used in clinical trials to accelerate drug development timelines and expeditiously bring effective treatment options to patients.

Alimentiv aims to design, test, and teach high-value strategies for treating Inflammatory Bowel Disease. High-quality clinical trials reduce development timelines and costs as well as investigator and patient burdens. Our Medical Research &

Development (MR&D) group reaches these goals via efficient protocol design, clinical and imaging endpoint development, and global Inflammatory Bowel Disease (IBD)/clinical trial education programs. The team of clinical epidemiologists, fellows, and statisticians publish their research regularly in high-impact, peer-reviewed journals. In addition, the team collaborates with a global network of GI expert partners in an outcome measure validation program and its implementation in clinical trials.

Alimentiv is the pioneer in validating and implementing endoscopic, histologic, and MRE central image scoring indices for GI trials. These validated endpoints and imaging technologies translate into Alimentiv being the global leader in central endoscopy reading services. Our data from this program have shown that central reading reduces the placebo response and increases data quality.

Alimentiv's Medical Directors also participate in regulatory agency educational symposia and consult on submissions for drug approval. These activities are carried out in accordance with our vision to perform high-quality multi-center randomized controlled trials that assess issues of importance to human health.



Commitment to GI

Leading the way in improving clinical research in gastroenterology.

Alimentiv has been on the front edge of academic research excellence since 1986. Under the leadership of Dr. Brian Feagan, Senior Scientific Director, and a key opinion leader in IBD clinical trials, Alimentiv established a track record in the execution of multi-center IBD clinical trials. Drs. William Sandborn and Geert D'Haens joined the Alimentiv team in 2011, thereby reinforcing Alimentiv's global expertise in IBD. In 2017, Alimentiv expanded into the research areas of eosinophilic gastrointestinal disease (EGID) and nonalcoholic steatohepatitis (NASH).

Alimentiv's MR&D division, led by Dr. Vipul Jairath, supports companies developing new therapies as a one-stop-shop for data-driven medical and clinical trial methodology expertise. Our expertise can be applied to solutions around imaging outcome design and/or the complexities of their operational implementation across the globe on your trials.

Scientific Leadership

Vipul Jairath
MBChB, DPhil, MRCP, FRCPC
Chief Medical Officer

Brian Feagan
MD, FRCPC
Senior Scientific Director

Geert D'Haens
MD, PhD, AGAF
Scientific Advisor

Research Expertise in Endpoint Validation and Implementation

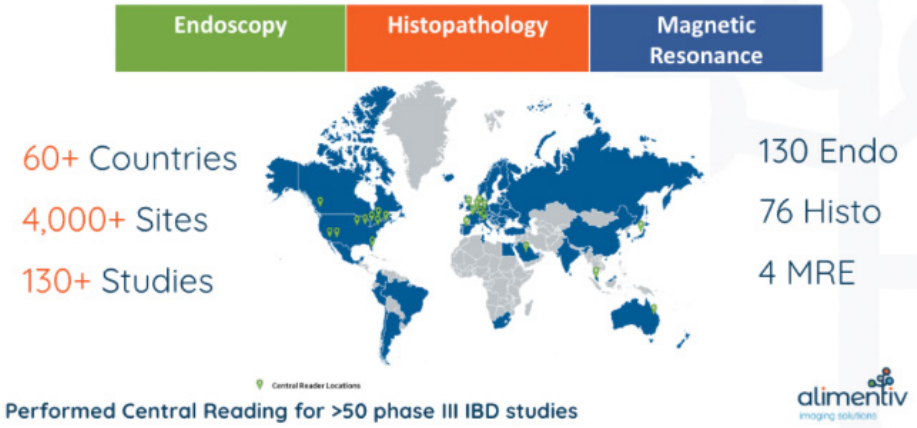
Combining research expertise with Medical Imaging operational excellence

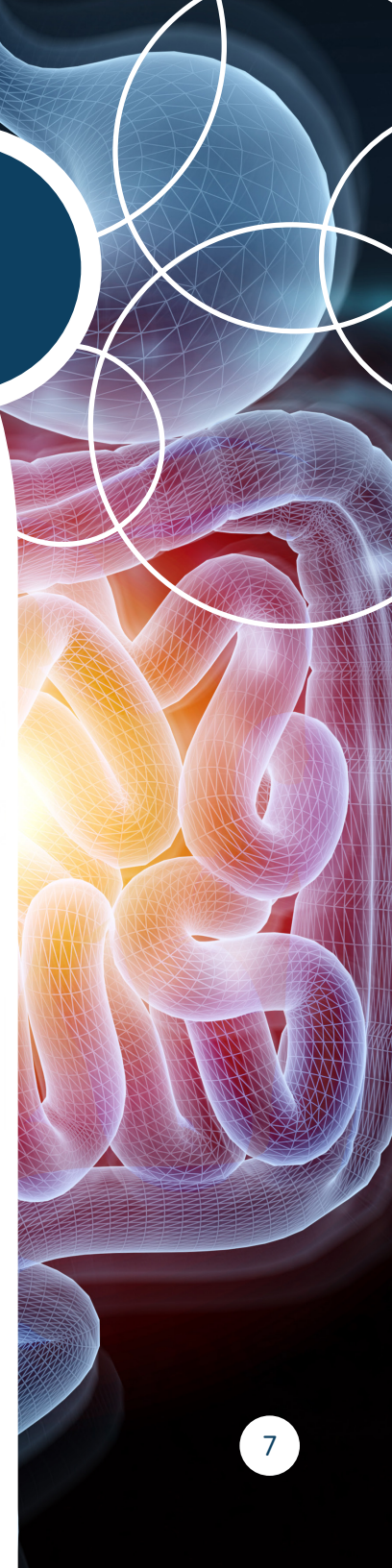
Alimentiv's Medical Research and Development (MR&D) division help companies develop new therapies as a one-stop-shop for data-driven medical and clinical trial methodology expertise. Our expertise can be applied from imaging outcome design to the complexities of operational implementation across the globe in all phases of clinical trials.

Alimentiv's scientists aim to design, test, and teach high-value strategies for treating GI diseases to reduce both development timelines and costs, as well as investigator and patient burdens. Our team assists you in attaining these goals through efficient protocol design, clinical and imaging endpoint development, and global GI/clinical trial education programs.

Medical Imaging expertise since 2007

Alimentiv is headquartered in London (Ontario, Canada) with offices in San Diego (California, United States) and Amsterdam (the Netherlands) providing global coverage for our services. Our central image management work has involved over 4,000 sites across more than 60 countries requiring the processing of greater than 60,000 endoscopic video recordings from Australia, North America, Europe, Southeast Asia, South America, and Africa.





CIMS Development

Alimentiv's CIMS solutions include products and services to consistently acquire and process endoscopy videos, histopathology images, and magnetic resonance images for blinded central review.

The development work of CIMS began in 2007 with Endoscopy when Alimentiv acted as the central coordinating center for endoscopic assessments for a trial recruiting patients from approximately 20 IBD sites in the US. Development of CIMS continued with application in global clinical development programs for both UC and CD, where it was used as a central quality control and screening tool to confirm subject eligibility. Alimentiv worked with IBD content experts, including but not limited to, Dr. Edward Loftus at the Mayo Clinic, Dr. William Sandborn at the University of California San Diego, and Dr. John McDonald at Western University on the development of training materials and procedures for CIMS.

Central endoscopic evaluation of patients in clinical trials is a reliable process that decreases enrollment bias and placebo rates. This represents a critical study of success factors as an accurate and reliable assessment of mucosal healing is a regulatory requirement of contemporary IBD trials.

Building further upon our Endoscopic expertise in the assessment of mucosal healing, Alimentiv has partnered with leading laboratories to offer Histopathology services, an integrated sample management/software/service solution that facilitates biopsy, processing, digitization, and the secure sharing of histopathologic images to facilitate central review and scoring. Microscopic inflammation is a key driver of disease relapse and a predictor of poor outcomes. Histologic assessment may eventually prove to be the gold standard for the measurement of disease activity.

In 2015, Alimentiv partnered with Jordi Rimola, MD, PhD, a specialist in radiology at the Hospital Clinic of Barcelona, Spain, to develop a novel imaging solution for Magnetic Resonance Enterography (MRE). MRE has high diagnostic accuracy, does not require exposure to ionizing radiation, and is considerably less invasive than endoscopy, which is important, given the need for serial assessments in clinical trials.

The ability of MRE to assess disease activity beyond the endoscope in clinical trials may lead to the inclusion of a broader patient population, improved patient selection, patient retention, and patient safety, as well as more efficient detection of treatment effects.

As part of our commitment to the continuous development of imaging solutions and assessment methodologies, Alimentiv actively works with key opinion leaders to improve the quality and reliability of image and assessment data throughout the GI research world.

CIMS Endoscopy

The Alimentiv CIMS Endoscopy solution is the most widely recognized solution for global UC and CD trials.

Alimentiv's solution for central image management is our CIMS technology which facilitates video assessment of endoscopic disease activity and is the most widely recognized, integrated hardware/software/service solution for global clinical trials. Alimentiv has achieved this through the facilitation of endoscopic procedure video acquisition, processing, publishing, and the secure sharing of videos to facilitate central review.

Alimentiv has developed an FDA-regulated 21 CFR part 11 compliant system to help ensure that endoscopy video and scoring data are fully auditable from the moment of video creation to the communication of scoring and assessment results. A trial-specific video capture kit is used by each participating site to capture the endoscopy procedure video. Unlike conventional recording technology, video recordings are generated and accessed only by those with credentials to access study equipment. Additionally, video recordings in the CIMS system are securely encrypted from the time of creation until processing and review. We guarantee that Protected Health Information (PHI) is made available only to authorized users. Video and data files cannot be edited throughout the chain of data custody.

Alimentiv customizes our CIMS kits to meet our client's needs by developing software, reference, and training materials to accompany our video capture equipment.

Endoscopy Key Benefits:

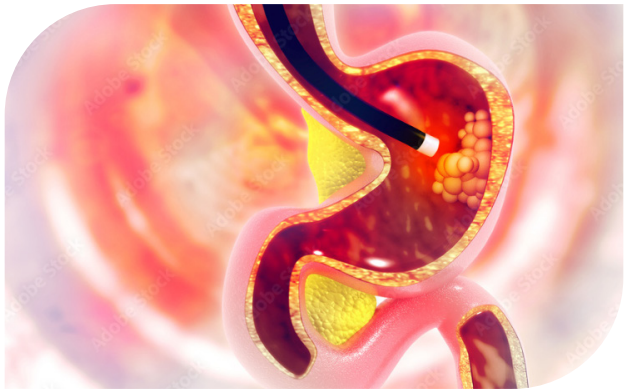
- 21 CFR part 11 compliant video capture solution
- Expert Central Readers: Our gastroenterologists are selected for their therapeutic area experience and trained using standardized disease activity scoring conventions and are regularly monitored for inter and intra- observer agreement metrics to identify reader drift and reduce variability.
- User-friendly one cable connection & video preview window to show what is being recorded on the device
- Backup-up video capture device included in every kit
- Built-in video Landmarking and Biopsy Snapshot Device
- 24/7 Help Desk available, translation available

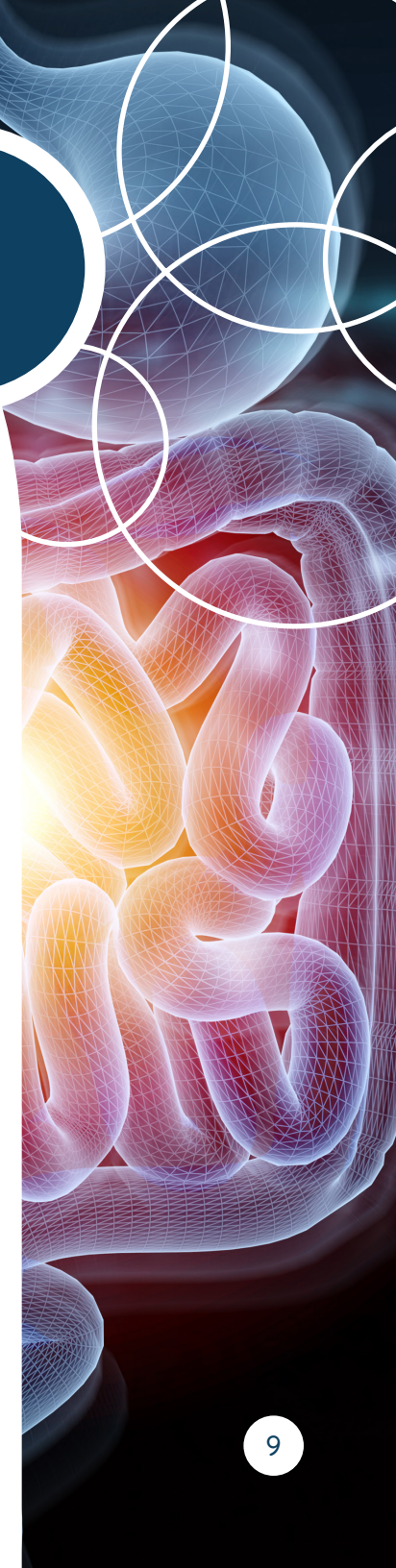
Indications:

- Crohn's Disease
- Ulcerative Colitis
- Pouchitis
- Eosinophilic Gastrointestinal Diseases (EGID)

Scoring Indices:

- SES-CD
- CDEIS
- Mayo Endoscopic Subscore (MES)
- UCEIS
- EREFS





CIMS Histopathology

Alimentiv's histopathology solution includes integrated biopsy sample management, image management software, and centralized assessment.

Alimentiv partnered with international expert GI pathologists and leading imaging software developers to offer a distinctive and competitive service for centralized histological assessment of disease activity. Our histopathology solution starts with tissue processing, digitization of slides, and utilization of our proprietary image management software solution: Lucidity.

Lucidity is a 21 CFR part 11 compliant technology that ensures slide images are fully auditable, protected, and reliable. Once uploaded to Lucidity, images are securely encrypted, quality controlled and made available to our expert Central Readers to perform centralized assessment and enter their scoring data into a validated computer system for expedited data sharing to meet our client's needs.

Histopathology Key Benefits

1. **Expert Central Readers:** Our pathologists are selected for their therapeutic area experience and trained using standardized disease activity scoring conventions and are regularly monitored for inter and intra- observer agreement metrics to identify reader drift and reduce variability.
2. **Dedicated Laboratory/Professional Services:** State-of-the-art histopathology laboratory services coupled with experienced imaging and data management personnel provide trial Sponsors with a robust and truly end-to-end imaging service.
3. **Robust Process & Technology:** Lucidity automates critical tasks within the imaging workflow, ensures images are securely encrypted, free of confidential identifiers, and that every action taken from image upload to central read is auditable.

Indications

- Crohn's Disease
- Ulcerative Colitis
- Pouchitis
- Eosinophilic Gastrointestinal Diseases (EGID)
- Nonalcoholic Steatohepatitis (NASH)

Scoring Indices

- Geboes Score
- Robarts Histopathology Index (RHI)
- Nancy Histological Index (NHI)
- Pouchitis Disease Activity Index (PDAI)

- Global Histologic Disease Activity Score (GHAS)
- Visual Analogue Scale (VAS)
- Eosinophilic Esophagitis Histologic Scoring System (EoHSS)
- Peak Eosinophil Count (PEC)
- NAFLD Activity Score (NAS)
- NASH Clinical Research Network (CRN) Fibrosis Score

Alimentiv collaborates with the sponsor-selected central laboratory and Alimentiv's sister company, AcelaBio, a state-of-the-art research laboratory to determine roles and responsibilities in the collection, shipment, and processing of tissue samples for the successful delivery of central image management of histopathology services.

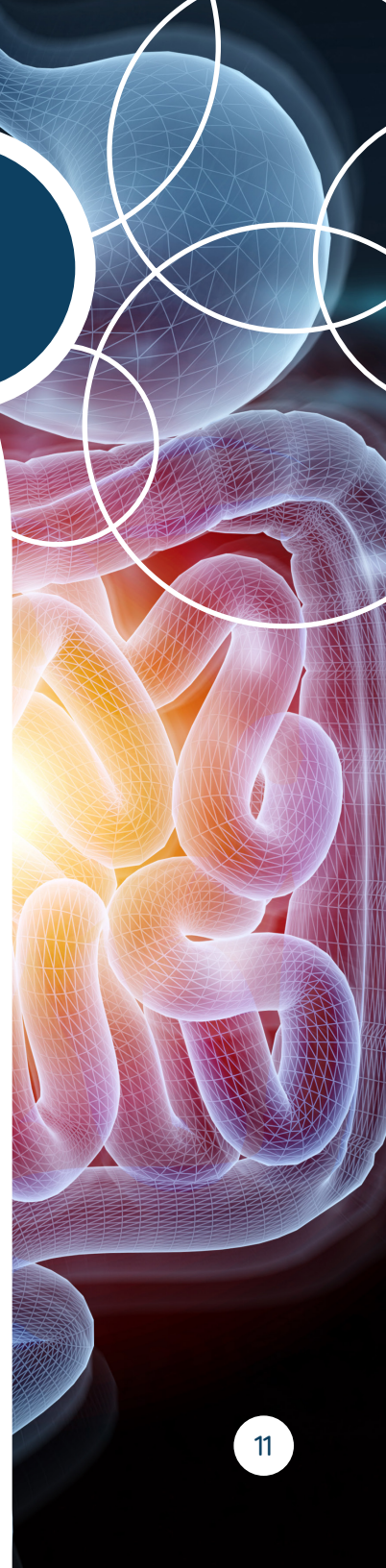
AcelaBio

AcelaBio is a commercial state-of-the-art research laboratory delivering histopathology and precision medicine services for GI global clinical trials located in San Diego (California, United States). It is wholly owned by the Alimentiv Health Trust and was created to meet the growing clinical research demand for quality and efficiency in laboratory service. Since AcelaBio is a sister company of Alimentiv, there are several benefits to this relationship:

- Optimized vendor relationships,
- Operational flexibility to meet the needs of clients,
- Alignment of systems, processes, and communication,
- Deliver a seamless end-to-end digital pathology solution from sample to score.

AcelaBio is built on deep expertise in clinical and precision medicine research to accelerate biomarker discovery and development. AcelaBio employs medical, scientific, and operational experts who are dedicated to delivering reliable, high-quality data and digital pathology. By investing in people, facilities, and technology, AcelaBio provides end-to-end histopathology and precision medicine services that meet regulatory standards to support the development of safe and effective therapies for patients.

AcelaBio's pathology workflow is fully digital and includes automated sample tracking with documented audit trails from sample receipt to sign-out. AcelaBio's team brings expertise in providing clinical trial services, pharmaceutical research, biotechnology, government agencies, and the investigator community.



CIMS MR

A safer, non-invasive method for disease activity assessment is available. Magnetic resonance imaging has high diagnostic accuracy, does not require exposure to ionizing radiation, and is considerably less invasive than endoscopy, which is important given the need for serial assessments in clinical trials. The ability of MR to assess disease activity beyond the endoscope in clinical trials may lead to the inclusion of a broader patient

population, improved patient selection, retention, safety, and increased efficiency to detect a treatment effect. Alimentiv has added this low-risk, non-invasive imaging option to our array of client solutions, and we have partnered with international expert radiologists for the centralized assessment of MR images.

Recognizing the growing need for non-invasive evaluation in IBD, Alimentiv partnered with leading radiologists to develop a Magnetic Resonance imaging solution for early phase trials. Alimentiv is committed to working towards having a 21 CFR part 11 compliant MR solution available by the end of 2023.

Indications

- Perianal Fistulizing Crohn's Disease
- Small Bowel Crohn's Disease
- Fibrostenotic Crohn's Disease

Scoring Indices

- Van Assche
- Magnetic Resonance Index of Activity (MaRIA) Scoring System
- Magnifi-CD
- Constrict score
- Stricturing Radiology Index (SRI)

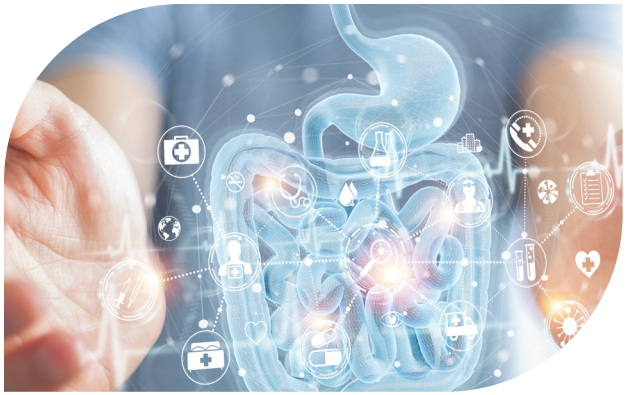
Project Management Team

We believe projects are most successful when the sponsor, the CRO (if applicable), and the Image Management Organization have clearly defined roles and responsibilities as well as establish clear lines of communication. This allows for the development of interdependent working relationships with a sense of joint ownership.

A Message From Courtney Sweet, VP, Medical Imaging

Medical Imaging is a rich part of our history, first as Robarts Clinical Trials and now as Alimentiv. We are proud of our Leading With Science ethos and commitment to reinvesting profit into research that transforms human health including the development of the Robarts Histopathology Index (RHI), and the development of Patient-Reported Outcome Measures (PROs) and for Ulcerative Colitis and Crohn's Disease.

Our Imaging Project Management team is available to assist on projects large and small to facilitate start-up, customize the imaging solution to meet study-specific needs, and report progress throughout the project lifespan. Our network of interdisciplinary teams works together to customize each imaging solution and facilitate image processing and centralized assessment of videos and/or images to ensure efficient and reliable delivery of results to our clients.



Imaging Project Management

To ensure a successful implementation, our clients are provided with a dedicated Imaging Project Management team consisting of a Project Director, Project Manager, and Project Coordinator.

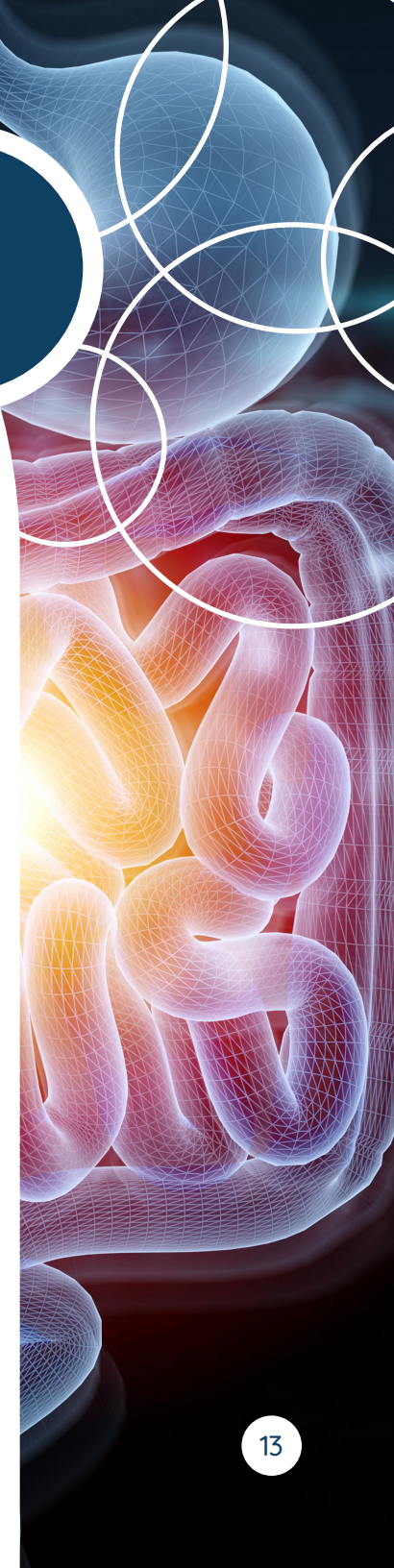
Service Desk

Our service desk team is the first point of contact for investigators, clinical sites, and sponsors for support requests for equipment, server access, video processing, and video results. We are available 24 hours, 7 days per week, 365 days a year for all parts of the world with the availability of real-time translations to assist with incoming queries in a timely manner.

Centralized Assessment

Central Readers are gastroenterologists, pathologists, and radiologists located across the globe experienced in reading endoscopy videos and digitized histological and MR images. They are knowledgeable in outcome scoring for the therapeutic indication being assessed to provide reliable independent, blinded centralized assessment.

They receive ongoing training in scoring indices and testing to ensure consistency in their assessments. Alimentiv works with our clients to determine the appropriate reading paradigm and number of Central Readers suited for each protocol to improve the quality and validity of endpoint assessment.



Data Management

An experienced Clinical Data Management team will work closely with you to develop an eCRF specific to the central assessments for your trial. Our data team is highly motivated to provide innovative and creative solutions. Support continues during the trial lifecycle through reporting, data review, and reconciliation, with a focus on delivering quality, consistent, and complete data.

Logistics

Our Logistics team works to provide a comprehensive service to clients in over 60 countries around the world and has extensive experience supporting clients throughout every step of the equipment management process in close collaboration with the Imaging Project Management department. Expert members of our Logistics team prepare raw materials and stage study-specific software to ensure equipment is site-ready while leveraging their thorough understanding of the many and varied rules and regulations of global exportation to ensure our CIMS video capture kits are delivered swiftly.

Our in-house logistics system allows us to track and trace equipment throughout the life cycle of any given study, during which we monitor its usage to anticipate a site's equipment needs before any issues appear, eliminating downtime for our clients. Our team works closely with the Service Desk team to offer site support for any changes in equipment requirements during the length of a study.

We welcome the opportunity to meet with you and discuss your needs.

Sincerely,
Courtney Sweet
VP, Medical Imaging
Alimentiv Inc.

alimentiv™

Discovery Accelerated.