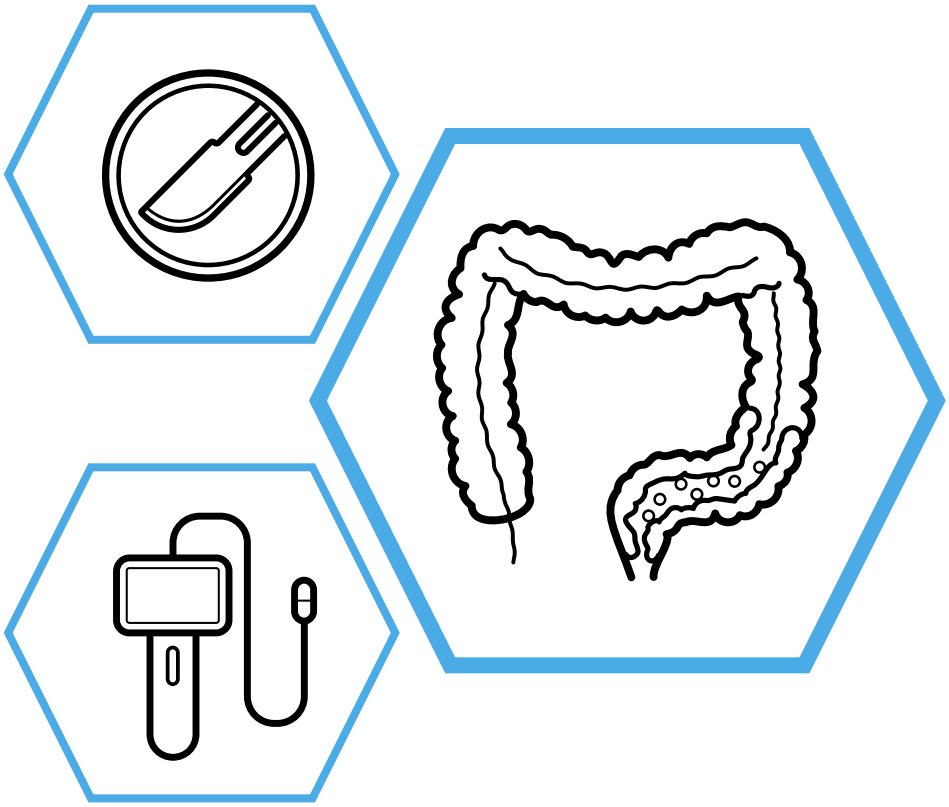
WHITEPAPER

Ulcerative Colitis: Considering the role of Histology and Endoscopy through trial phases

2025



Perspectum

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Introduction

Ulcerative Colitis (UC) is a chronic and relapsing condition whose global prevalence continues to rise. This epidemiological trend has intensified both the clinical and economic burden of disease, driving demand for more effective therapies. As competition grows and regulatory expectations become more exacting, sponsors face mounting pressure to demonstrate meaningful, reproducible treatment effects in late-phase studies.

Historically, treatment efficacy in UC trials has been evaluated using symptom-based indices such as the Mayo Score[1]. While useful in capturing patient-reported outcomes, these tools correlate poorly with underlying inflammation in the gut and do not predict the likelihood of disease flares. Additionally, reporting subjectivity has limited their value as surrogate endpoints[20]. In response, objective, biologically grounded measures are increasingly being used as endpoints in UC trials. Endoscopic assessment has emerged as the regulatory gold standard for mucosal healing, while histology is gaining prominence as a complementary endpoint that offers greater sensitivity to residual disease activity and stronger predictive value for durable remission[1,2,3,4,5,6].

Yet while these endpoints promise enhanced rigor, they also introduce operational complexity. Variability in endoscopy acquisition, biopsy collection, and inter-reader variability can dilute treatment effects and inflate placebo responses[10]. Without robust operational frameworks, sponsors risk undermining the very endpoints that regulators value most.

Several solutions aim to address these challenges. Validated histologic and endoscopic indices, centralized independent review, and AI are improving standardization, reducing variability, and enabling scalable workflows across global clinical trials. Vendors with proven expertise in delivering these solutions at scale now play a pivotal role in ensuring that trial data are not only high-quality but also regulator ready.

This white paper explores the strategies sponsors need to succeed, including the role of endoscopic and histologic endpoints, the value of central reading, the integration of histology into trial design, and the operational decisions that underpin trial credibility.

Current Primary Endpoint: Endoscopy

Endoscopy as the Regulatory Gold Standard

Endoscopic assessment has become the cornerstone of efficacy evaluation in UC clinical trials. Its role is grounded in the strong correlation between mucosal healing and clinically meaningful outcomes such as sustained remission and reduced relapse rates[6]. Regulators now expect the demonstration of endoscopic healing[3,12] in pivotal Phase III studies, making it a central determinant of approval and product differentiation. What was once considered an exploratory measure in early-phase development has evolved into a definitive benchmark that sponsors must address in their trial strategies. Yet, the continued reliance on endoscopy presents a set of complex challenges. Multiple scoring systems are in use, each with distinct advantages and limitations. Decisions about which system to adopt are therefore not purely operational but strategic, influencing regulatory credibility, trial efficiency, and competitive positioning.

> Regulators now expect the demonstration of endoscopic healing in pivotal Phase III studies

Comparative Landscape of Scoring Systems

The two most widely applied indices for UC are the Mayo Endoscopic Subscore (MES) and Ulcerative Colitis Endoscopic Index of Severity (UCEIS)[14] Both the FDA and EMA emphasize the use of objective endoscopic assessment in efficacy but do not mandate a single scoring system; approaches are acceptable if they are reliable, validated, and operationally well-controlled[3,9,12].

MES has emerged as the preferred index for late-phase programs and appears in FDA guidance as an acceptable way to demonstrate endoscopic improvement and/or remission within composite endpoints[3], making it a low-risk choice for pivotal clinical trials from a regulatory perspective. The MES is also preferred operationally due to its simple 4-point scale. This simplicity makes it straightforward to train and deploy at scale, aligning it with both the FDA's emphasis on objective, reproducible measures, and the EMA's expectation to demonstrate mucosal healing using standardized endoscopic findings.

By contrast, UCEIS offers greater granularity (with a score ranging 0-8) and can detect subtle differences in vascular patterns, bleeding, and erosions/ulceration. This offers

greater sensitivity to change, particularly when distinguishing between complete and near-complete remission, but requires more training and consistency to satisfy the same reliability requirements in a multi-centre setting[13,14].

The choice between these systems is therefore not simply technical. Selecting a more established measure may maximize regulatory acceptability, while adopting a more sensitive system can signal innovation and potentially increase sensitivity, but should be paired with strong standardization efforts and a clear validation rationale to meet FDA/EMA expectations of reproducibility and interpretability. Sponsors who strike the right balance stand to gain both in regulatory negotiations and in differentiation from competitors.

The Importance of Infrastructure and Independent Review

Endoscopic endpoints derive their credibility not only from the choice of index but also from the infrastructure supporting their implementation. Centralized independent review of endoscopic video has become an expectation in late-phase trials, ensuring consistency, minimizing site-level bias, and producing datasets that withstand regulatory scrutiny. Early engagement with specialist vendors is therefore critical.

Vendors with proven capabilities in blinded central reading, standardized protocols, and calibration workshops can markedly reduce inter-observer variability. Increasingly, leading vendors are integrating artificial intelligence into workflows to enhance quality control and reader alignment. These capabilities transform vendor selection from a logistical afterthought into a strategic decision that should be made at the earliest stages of trial design.

Considerations for Trial Design

In Phase III IBD trials, one of the biggest challenges is defining remission in a way that is both rigorous and achievable. For UC, regulators increasingly expect stringent definitions of mucosal healing, i.e. an MES of 0 or 1 (where 1 does not include friability) or equivalent UCEIS thresholds. While such strict definitions align with regulatory standards and clinical expectations, they represent a high bar for trial success, as relatively few patients may reach this level of healing. Sponsors therefore need to balance two priorities: setting endpoints that satisfy regulators, patients and clinicians, while also ensuring the trial remains statistically feasible and adequately powered.

Timing is equally critical. Assessments in the induction phase, typically around weeks 12 to 14, establish early mucosal response, while evaluations at week 52 or at study conclusion confirm the durability of healing[3,12]. Optional interim assessments may

provide valuable insights into treatment dynamics but add operational complexity and risk patient engagement. Ultimately, the timing of endoscopic endpoints should be aligned with the pharmacodynamics of the investigational product to maximize interpretability and regulatory impact.

Emerging Regulatory Preference for Composite Endpoints

From Exploratory to Regulatory Expectation

Regulatory agencies are increasingly clear that UC trials must demonstrate more than symptomatic relief: they must also show that therapies modify the biology of disease. Endoscopic and histologic measures of mucosal healing have therefore moved from exploratory use in early-phase studies to critical tools in late-phase development[7]. Sponsors are now expected to integrate these endpoints in Phase IIb and Phase III programs, often as key secondary, or, in some cases, as co-primary efficacy measures. When applied together, endoscopy and histology provide a rigorous, regulator-acceptable framework for assessing treatment effect and positioning therapies competitively.

Complementary Perspectives: Macroscopic and Microscopic Healing

Endoscopy and histology offer distinct but complementary insights. Endoscopy provides a macroscopic view of mucosal healing, enabling assessment of visible ulceration, friability, and vascular pattern. Histology, by contrast, captures a microscopic view of epithelial repair and residual inflammation. This granular perspective can detect subtle or early responses invisible to endoscopy and uncoupled from clinical symptoms[15,16,17,20].

The clinical significance of this dual perspective is well documented. Patients with persistent histologic activity despite apparent endoscopic remission face higher relapse rates, increased corticosteroid dependence, and worse long-term outcomes[7,8]. Such findings underscore histology's value in defining the *depth* and *durability* of remission.

> Patients with persistent histologic activity despite apparent endoscopic remission face higher relapse rates and worse long-term outcomes

Histology's Evolving Role in Regulatory Strategy

Despite its clear utility, histology has historically been underutilized and inconsistently applied, often in the context of secondary or exploratory endpoints. This is now changing. Academic consortia and regulators increasingly recognize histologic remission as a meaningful endpoint[3,9,12], supported by validated scoring systems such as the Geboes Score (GS), Nancy Index (NI), and Robarts Histopathology Index (RHI). These frameworks provide structured, reproducible methods for quantifying tissue-level disease activity, giving histology the credibility to stand alongside endoscopy in regulatory pathways.

For sponsors accustomed to traditional clinical and endoscopic measures, histology may initially appear supplementary. In practice, when implemented strategically, it provides additional evidence that further strengthens confidence in efficacy outcomes and is becoming common in late phase trials a as a co-primary or key secondary endpoint.

Building Capability for Composite Endpoints

Integration does not require immediate elevation of histology to a co-primary role. Sponsors can begin by including histology as a secondary or exploratory measure in Phase I and II programs, using these early trials to pilot workflows and validate scoring systems. Over time, building toward composite endpoints that combine histology, endoscopy, and clinical measures creates a multidimensional framework for defining therapeutic benefit.

Strategic Implications for Sponsors

The movement toward composite endpoints reflects both scientific logic and regulatory momentum. By aligning macroscopic and microscopic healing, sponsors provide a more comprehensive and clinically relevant demonstration of efficacy. This layered approach enhances sensitivity to treatment effects, reduces regulatory risk, and strengthens differentiation in a crowded therapeutic landscape. For some assets, it may even accelerate approval pathways by providing earlier, more robust evidence of disease modification.

Histology as a Complementary Efficacy Endpoint

Embedding Histology as an Endpoint

As we have seen, histology has become a key part of the development strategy. The challenge for sponsors is not whether to include histology, but how to do so effectively. Selecting the appropriate scoring system, managing intertwined histological and endoscopic operations and integrating findings have become a strategic decision, shaping both regulatory acceptance and competitive positioning.

Comparative Landscape of Histologic Scoring Systems

Several indices have emerged, each with its own balance of sensitivity, complexity, and practicality:

- **Geboes Score (GS)** remains the most established, widely validated, and frequently referenced in regulatory discussions. It offers detailed characterization of inflammatory activity, although its depth comes at the cost of time-intensive scoring and potential variability near remission thresholds[2]. A simplified version has been adopted in high-throughput contexts, though this risks losing sensitivity to subtle improvements.
- **Nancy Index (NI)** provides a simplified 5-point scale, with remission defined as a score of 0 or 1. Its ease of use and reproducibility make it attractive for large late-phase programs, but the trade-off is limited granularity, particularly in distinguishing between mild and moderate disease.
- **Robarts Histopathology Index (RHI)** is increasingly favored for its sensitivity and nuanced assessment. By weighting multiple histologic domains, it provides greater precision in defining partial versus complete healing[2]. This sophistication, however, demands higher emphasis on alignment amongst central readers as well as greater training and administration.

Table 1 - Comparison between common clinical trial histopathology scoring systems

Scoring System	Strengths	Limitations	Clinical Trial Relevance
Geboes Score	Gold standard in regulatory discussions Widely validated across trials Sensitive to subtle histological changes	Time-intensive Higher variability near remission Less practical in large Phase 3 programs	Strong regulatory credibility; often referenced in FDA/EMA reviews. Best suited for early-phase or mechanistic studies where granularity is critical.
Nancy Index	High reproducibility Rapid and simple Well-suited for multicentre Phase 3 trials	Limited granularity Less sensitive to partial healing or subtle changes	Increasing adoption in late-phase pivotal studies. Balances reproducibility and feasibility for large cohorts.
Robarts Histopathology Index	Sensitive and nuanced Better distinguishes partial vs complete healing Increasingly cited in modern trials	Requires trained central readers More complex to administer Standardization critical	Attractive for next-generation endpoints; growing favour in mid-to-late phase studies where precision in defining healing is required.

Just as with endoscopic indices, the choice of histologic score represents a trade-off between regulatory familiarity, operational feasibility, and scientific ambition. GS remains the “safe” option, NI the pragmatic choice for scalability, and RHI the forward-looking measure that signals innovation but requires investment in trial management.

Integrating Endoscopic and Histologic Endpoints

Histology is most powerful when integrated with endoscopic assessment, presenting a multidimensional picture of mucosal healing. Sponsors who design trials around cohesive strategies, rather than treating histology as an isolated secondary or exploratory measure, strengthen both their regulatory submissions and their clinical narratives.

Several considerations shape this integration:

- **Composite Endpoints:** Dual endpoints that combine endoscopic remission (e.g., MES = 0 or 1 without friability) with histologic remission (e.g., GS ≤ 2 or NI ≤ 1) provide compelling evidence of biological efficacy.
- **Statistical Hierarchy:** Clear sequencing of endpoint testing preserves statistical power and aligns with regulatory expectations, typically prioritizing endoscopic outcomes while allowing histology to reinforce findings.
- **Operational Standardization:** Centralized review, harmonized biopsy and endoscopy protocols, and effective quality control are essential to ensure reproducibility and minimize variability across global sites.
- **Narrative Cohesion:** The most persuasive regulatory submissions emphasize the concordance of macroscopic and microscopic healing, transforming two endpoints into a unified story of therapeutic benefit.

Looking Ahead: The Evolving Role of Histology

Histology is set to play an increasingly prominent role in late-phase UC development. As our understanding of this complex condition evolves, the expectation of histology as a co-primary or key secondary endpoint will likely grow.

In the longer term, histology may serve as a bridge between traditional visual assessments and biomarker-driven approaches, enabling multidimensional definitions of disease modification. Sponsors who invest early in centralized infrastructure and histology-capable vendor partnerships will not only meet emerging expectations but also future-proof their development strategies.

Tackling Reader Variability

The Problem: Variability Dilutes Efficacy Signals

As endoscopic and histologic endpoints assume greater prominence in UC trials, the challenge of variability in local assessments becomes increasingly consequential. Endoscopy and histology are inherently subjective: interpretation differs between readers, particularly across diverse trial sites, each with a natural bias sites have for their own patients. High variability weakens efficacy signals, inflates placebo response, and undermines statistical power. In pivotal Phase III studies, such inconsistencies pose a direct risk to regulatory approval, threatening to obscure genuine therapeutic benefit.

> Central reading is no longer optional, but an essential requirement

The Solution: Central Reading for Consistency and Objectivity

Central reading provides a structured solution by ensuring blinded, standardized evaluation of endoscopy and biopsy data by independent experts[10,22]. This model delivers two essential benefits: consistency in applying scoring criteria and protection against site-level bias.

The impact of central reading is well-documented. In a landmark study by Gottlieb et al. (2015), the use of central endoscopic review reduced placebo response rates from 20.6% to 13.8% and increased detectable treatment effects from 9.4% to 15.2%[22]. This illustrates how central reading strengthens both data quality and statistical power. Experiences across sponsors and CROs reinforce the same conclusion: central reading no longer optional, but an essential requirement.

Comparing Reading Strategies: Why Perspectum Recommends a 2+1 Model

There are several different central reading strategies ranging from single reader to complex multi-reader panels. Many late phase programs adopt a 2+1 model adjudication strategy, whereby two independent readers assess each case, and a third resolves discordance where necessary.

This approach balances statistical robustness, operational feasibility, and regulatory alignment. A single-reader model lacks safeguards against subjectivity, while large

panels of readers are costly and operationally complex. The 2+1 strategy achieves cost-effectiveness without compromising data integrity, creating a workflow that scales reliably across large multi-centre studies. Both the FDA and EMA emphasize the importance of objective, reproducible endpoints and the 2+1 model has emerged as an effective standard to meet this expectation.

Optimizing Central Reading

Regardless of the central reading strategy, sponsors can use several proven tactics to maximise reader alignment and maintain it throughout the trial. These practices increase consistency, reduce variability, and ultimately strengthen the trial.

- Establish a reading plan: Scoring systems are inherently open to interpretation, and pathologists bring varied experience. Facilitated consensus discussions clarify each scoring criterion, remove ambiguity and document agreed standards. This reduces inter-reader variability, and in turn reduces the number of cases requiring a third, tiebreaker, read or a consensus meeting.
- Conduct a baseline alignment assessment – Before central reading begins, having readers assess a set of non-trial cases establishes a baseline alignment measurement. This ensures the trial begins with readers already calibrated to a sufficient standard and highlights any discrepancies that require resolution.
- Track alignment continuously – Throughout the trial, alignment should be monitored against baseline. If drift occurs, sponsors can intervene by returning to the reading plan and introducing additional training cases. This active feedback loop preserves consistency, protects data quality, and ensures trial integrity.

Why Early Adoption Matters

While central reading is viewed as a requirement for Phase III, introducing it earlier in development yields clear benefits. Piloting central reading workflows in phase II studies allows sponsors to:

- Reliably demonstrate drug effect early, strengthening the case for progression to Phase III.
- Validate emerging endpoints, such as histologic remission, under controlled conditions.
- Standardize acquisition and reading protocols before broad geographic expansion.
- Test and refine vendor partnerships.

- Identify and address logistical bottlenecks before implementation in pivotal programs.

By Phase III, these systems are already in place, reducing risk and accelerating execution. Early adoption is therefore not an operational preference, but a strategic choice that de-risks the entire development lifecycle.

Sponsor Concerns and Practical Solutions

Although adopting a central reading strategy may introduce additional cost, complexity, or implementation burden, the risks of inconsistent local reads - missed efficacy signals, inflated placebo responses, failed endpoints, or regulatory pushback – far outweigh these barriers.

With strategic planning, central reading can be scaled proportionately to trial size and integrated seamlessly into workflows. Experienced vendors mitigate implementation challenges through established SOPs, secure data transfer platforms, and built-in quality assurance. Ultimately, the greatest risk is not the cost of central reading, but the cost of failing to implement it.

AI: Opening New Opportunities for UC Trials

Artificial intelligence (AI) is emerging as a critical enabler in the assessment of endoscopic and histologic endpoints[24,25]. By embedding AI within central reading workflows, sponsors can overcome the operational challenges that undermine consistency, while generating richer insights into treatment effect. Rather than replacing established processes, AI strengthens them, supporting readers, improving quality, and ensuring reproducibility across multiple readers.

> AI strengths processes – supporting readers, improving quality and increasing insight

Quality Control and Workflow Efficiency

In both histology and endoscopy, AI-driven quality control ensures that only complete, high-quality images enter the analysis pipeline[24,25]. Automated checks for clarity, protocol compliance, and slide preparation reduce the risk of site-level error and accelerate workflow. This allows large, multi-site studies to scale without compromising consistency or delaying endpoint assessment.

Reader Support and Alignment

Interpretation of images is inherently subjective, and variability between readers can dilute efficacy signals. AI mitigates this by highlighting regions of interest, flagging discordant assessments, and supporting calibration across large reviewer networks. By guiding rather than replacing human judgment, AI reduces variability, increases alignment, and preserves the integrity of central reading datasets[25].

Data Insight Beyond Traditional Scoring

Traditional ordinal scoring systems, while validated, capture only part of the therapeutic picture. AI enables the continuous, quantitative analysis of disease features, providing greater sensitivity to change. These additional data layers enhance efficacy analysis and support a more nuanced understanding of treatment response[26].

Strategic Value for Sponsors

For sponsors, the integration of AI into endoscopic and histologic workflows offers more than interesting data. It provides operational efficiency, safeguards data quality, reduces the risk of failed endpoints, and produces datasets that strengthen confidence in therapeutic effect. While regulators have not yet mandated AI approaches, their emphasis on reproducibility and objectivity makes AI a natural next step. In a competitive UC landscape, early adoption of AI provides scientific credibility, operational efficiency, and strategic differentiation, helping sponsors advance their programs with greater confidence.

Operational Delivery: A Strategic Foundation for Success

Why Operational Decisions Define Late-Phase Outcomes

Late-phase IBD trials demand not only scientific rigor but also flawless execution. Operational infrastructure is now a decisive factor in trial credibility. Weak vendor strategy, poor governance, or inadequate site readiness can dilute treatment effects, delay timelines, and jeopardize submissions. Conversely, robust operational frameworks reduce variability, mitigate risk, and scale reliably across geographies, enabling sponsors to maximize both evidentiary strength and competitive differentiation.

Vendor Models: Balancing Integration and Specialization

One of the earliest, and most strategic, decisions for sponsors is vendor selection. A single integrated provider can streamline contracting, centralize accountability, and harmonize workflows, but only if that partner has genuine end-to-end capabilities. By contrast, a multi-vendor approach allows sponsors to secure best-in-class expertise in discrete domains but introduces complexity, heightens oversight requirements, and risks data fragmentation.

Capabilities That Matter: From Generic Support to Specialist Expertise

Not all vendors are equipped for the unique demands of IBD trials. Sponsors must prioritize partners who:

- Provide direct experience with both endoscopy and histology in late-phase settings.
- Scale globally across multi-site networks without compromising quality.
- Deliver secure, compliant, and interoperable data flows that meet regulatory standards across jurisdictions.
- Enable real-time data transfer and centralized workflows to minimize delay.

Choosing a vendor without this depth of expertise risks operational drift – protocol deviations, inconsistent image quality, or data gaps that jeopardize regulatory review. Selecting one with proven capabilities ensures resilient infrastructure, streamlined workflows, and audit-ready datasets.

Innovation, Adaptability, and Risk Management

Late-phase trials are rarely static. Protocol amendments, evolving endpoints, and innovations require infrastructure that can adapt without disruption. Pragmatic innovation is key: piloting new tools early in development builds confidence, while embedding new tools in pivotal trials without prior validation carries risk. Sponsors who plan for adaptability future-proof their programs and accelerate the adoption of validated innovations; those who neglect it risks both obsolescence and operational inflexibility.

Site Excellence as a Determinant of Data Integrity

Sites are the frontline of data capture, yet variability in training, equipment, or protocols can erode trial quality. Standardized biopsy techniques, harmonized endoscopy protocols, and rigorous onboarding are essential. Equally critical is ongoing provision of support to prevent “quality drift” as studies progress. Proactive engagement turns sites from weak links into reliable data partners.

Data Governance and Regulatory Readiness

In an era of heightened security threats and privacy concerns, data governance is a strategic necessity. Encryption, audit trails, and compliance with regulations including GDPR, HIPAA, and 21 CFR Part 11 are mandatory baseline requirements. Both the FDA and EMA increasingly scrutinize data traceability and device validation, making robust governance imperative rather than a compliance formality. Sponsors that neglect these elements risk inspection findings, delayed submissions, and reputational damage.

> Operational infrastructure is now a decisive factor in trial credibility

The Ideal Vendor Profile

Taken together, these considerations define the attributes of the ideal partner for late-phase UC programs:

- **Integrated Capability:** End-to-end support for both endoscopy and histology within a unified workflow.
- **Proven Experience:** Demonstrated success across large, global trials with endoscopy- and histology-based endpoints.
- **Regulatory Alignment:** Platforms, protocols, and data systems validated to meet international standards.
- **Operational Scalability:** infrastructure that expands without delays or loss of consistency.
- **Innovation and Adaptability:** Ability to incorporate validated innovations and quickly while maintaining compliance.
- **Collaborative Partnership:** Technical delivery paired with strategic alignment and proactive problem-solving.

Sponsors who select vendors with this profile safeguard trial credibility, reduce operational risk, and accelerate approval pathways. Those who compromise, whether by relying on underqualified providers, fragmented vendor models, or insufficient infrastructure, risk costly delays, regulatory pushback, and diminished competitive advantage.

Conclusion: Setting the Stage for Success

Operational delivery is not a back-office function but a strategic pillar of late-phase IBD development. Every decision - vendor selection, site readiness, data governance, and adoption of innovation - directly shapes regulatory outcomes and market positioning.

Case Study – PTG-100

PTG-100, an oral α4β7 integrin antagonist, entered a global Phase 2b UC trial (PROPEL) using a two-stage adaptive design with 12-week induction and centrally read endoscopy. Following an interim analysis of the first 65 completers, the DMC recommended discontinuation for futility on the primary endpoint (clinical remission), driven by an unusually high placebo remission rate [28,30].

A subsequent blinded independent re-read of digitized endoscopies later identified human error at the original reading vendor [29,31]. When combined with the blinded histology reads pre-specified in the trial protocol, clear efficacy signals emerged: clinical remission rates of 9–16% across PTG-100 arms vs 4.8% with placebo; histologic remission (RHI ≤ 3) of up to 44% at the highest dose vs 0% with placebo (N=83) [27].

Despite these findings, the program was not restarted, a costly outcome in terms of time, investment, and patient opportunity. The case underscores how reader variability and QC failures can obscure genuine treatment effects and why adjudication, in-study alignment monitoring, and rigorous QC are essential safe-guards in late-phase UC trials.

Perspectum

Your Strategic Partner for IBD Trials

Perspectum is an experienced multi-modal imaging CRO providing standardized, innovative biomarkers to late-stage clinical trials. In UC, our central reading service for endoscopy and histology offers sponsors a fast, reliable solution that enhances trial efficiency and maximizes endpoint power. Enhanced by our proprietary AI, we deliver deeper insight, stronger data, and seamless operational execution.

Proven Complex Trial Experience

Late-phase UC trials demand not only operational rigor, but also strategic alignment, scientific depth, and adaptable infrastructure. Perspectum integrates all three. With experience in more than 80 interventional trials, including over 30 in Phase II/III, and currently delivering over 10 endoscopy and/or histology based late-phase studies across hundreds of global sites and thousands of cases each year, Perspectum has earned the trust of sponsors navigating complex endoscopic and histologic endpoints.

An Integrated, End-to-End Workflow

Perspectum delivers a cohesive platform that connects every stage of the trial lifecycle. From site onboarding and equipment support to acquisition, digitization, and central reading, each step is harmonized within a single operational framework. Real-time monitoring, embedded quality control, and rapid issue resolution ensure outputs remain consistent, traceable, and audit-ready from first patient in, to regulatory submission. For sponsors, this integration eliminates silos, reduces variability, and accelerates decision-making.

Purpose-Built Central Reading and Histology Infrastructure

Perspectum provides standardized pipelines for endoscopy video capture, slide preparation and digitization, quality control and central reading. Our off the shelf 2+1 and 3 reader workflows balance robustness with efficiency, reduced variability and amplifies treatment signals, while remaining customizable to requirements. Patient assessment is completed in just a few days with data made available to sponsors and sites automatically, maximising patient engagement and trial insights.

AI for Precision and Scalability

Innovation is embedded throughout our workflow to impact all aspects of trial delivery:

- Quality Control: automated checks ensure consistency and accelerate workflows.
- Reader support: AI-driven tools support the readers in both histology and endoscopy, improving alignment and powering endpoints.
- Data insight: Automated analysis delivers granular, quantitative disease metrics for exploratory endpoints, deepening trial insight.
- Workflow optimisation: Data-driven insights streamline processes, providing faster turnaround and higher quality results.

Our understanding of data empowers sponsors to deliver highly effective phase II and III trials with confidence.

Built for Compliance, Designed for Ease

Perspectum's platform is engineered with compliance and usability at its core. Fully aligned with 21 CFR Part 11, GDPR, and HIPAA, and certified to SOC 2 Type II and ISO 27001 standards, it provides the transparency, traceability, and security regulators demand. At the same time, user-focused design ensures rapid site and reader onboarding, intuitive workflows, and seamless engagement. Sponsors gain audit-ready assurance without operational friction.

Simplifying Operational Complexity

By uniting advanced technology, scientific expertise, and operational excellence in a single platform, Perspectum transforms the execution of IBD trials. We simplify the complexity of endoscopic and histologic endpoints, reduce operational risk, and strengthen the integrity of data packages for regulatory submission. The result for sponsors is confidence: confidence in data quality, in regulatory readiness, and in the success of their programs.

At Perspectum, we do not simply execute trials – we partner with sponsors to design and deliver smarter, more successful studies.

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