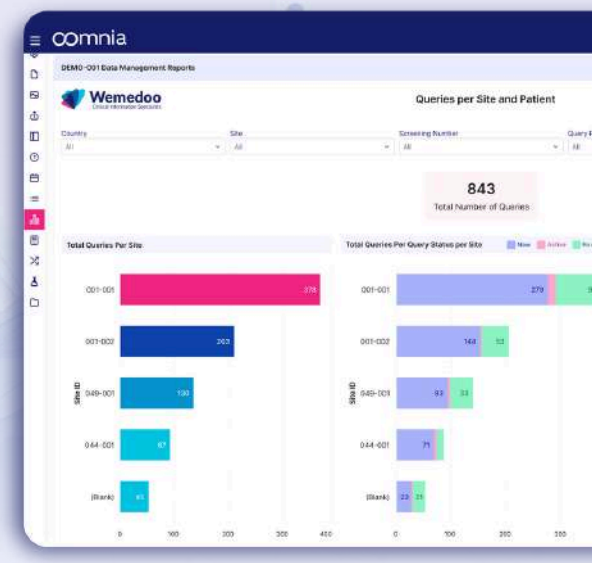
Unified clinical trial software for gastroenterology studies

One platform. Connected GI data. Built for complex disease pathways.



oomnia brings gastroenterology trials into a unified Clinical Research Information System (CRIS), enabling teams to coordinate symptom tracking, laboratory findings, procedural data, and operational workflows within one integrated environment from study start through completion

The operational reality of gastroenterology clinical trials

Fluctuating disease patterns over time

Gastrointestinal conditions often alternate between active flare-ups and remission. This variability makes it difficult to determine when to assess endpoints.

Combination of subjective and objective endpoints

GI studies depend on both patient reported symptoms and clinical measurements such as lab values and procedural findings

Procedural complexity within study workflows

Endoscopic procedures, biopsies, and imaging introduce additional coordination requirements, increasing burden on both patients and sites

Long-term follow-up and engagement demands

Many GI studies span extended periods, requiring continuous monitoring, consistent data capture, and sustained patient participation across multiple visits and procedures

High variability in site expertise and standardization

Differences in investigator experience, procedural techniques, and site capabilities can impact consistency in assessments and data collection

One connected system for gastroenterology trial execution

Integrates symptom data, lab results, and procedure derived findings into a single dataset

Supports protocol adjustments without disrupting ongoing study execution

Enables continuous tracking of disease activity across flares and periods of stability

Replaces disconnected systems with one coordinated workflow for sites, vendors, and sponsors

GI: Gastrointestinal

One platform for gastroenterology trial execution

Gastroenterology workflows, structured for continuity

oomnia brings clinical data capture, procedural tracking, and operational management together into a single system, ensuring that every aspect of a GI study remains aligned and traceable across time and stakeholders

EDC

Captures GI-specific data including symptom scores, laboratory results, endoscopy findings, and safety events with built-in validation

CTMS

Provides oversight into study progress, site performance, and operational timelines across gastroenterology programs

RTSM

Supports flexible patient allocation strategies aligned with disease severity, treatment arms, or subgroup definitions

eConsent

Enables flexible consent processes, supporting both site based and remote enrollment as well as protocol updates

eCOA / ePRO

Captures patient-reported GI symptoms, disease impact, and quality-of-life data longitudinally

eTMF

Maintains complete, audit ready documentation across complex and evolving gastroenterology trials

Patient engagement tools

Supports adherence and retention with reminders and communication designed for frequent assessments and long follow-up

Analytics and reporting

Combines clinical, laboratory, symptom, and procedural data into real-time dashboards for monitoring and analysis

GI: Gastrointestinal; EDC: Electronic Data Capture; CTMS: Clinical Trial Management System; RTSM: Randomization and Trial Supply Management; eConsent: Electronic Informed Consent; eCOA/ePRO: Electronic Clinical Outcome Assessment / Electronic Patient-Reported Outcome; eTMF: Electronic Trial Master File.

How oomnia fits into the gastroenterology study ecosystem

oomnia provides a central framework that connects clinical sites, procedural vendors, laboratories, and sponsor systems, enabling consistent data flow and coordination across all components of gastroenterology clinical trial

Built for regulatory and operational confidence

- 21 CFR Part 11–compliant data with full audit trails and secure electronic signatures
- Risk based quality management aligned with ICH E6(R3) guidance
- CDISC-aligned datasets supporting standardized reporting of GI endpoints
- Designed for global studies and submissions to regulatory authorities such as FDA and EMA

Measurable impact for gastroenterology clinical teams

Improved visibility into disease progression

Integrated data streams provide a clearer picture of symptom patterns, treatment response, and long-term outcomes

Reduced complexity in study operations

A single system simplifies coordination across sites, procedures, and data sources

More consistent and reliable datasets

Standardized data capture and validation reduce variability across symptom reporting, labs, and procedures

Better support for long-running studies

Connected workflows and patient engagement tools help maintain continuity throughout extended follow-up periods

ICH E6(R3): International Council for Harmonisation Guideline for Good Clinical Practice (Revision 3); CDISC: Clinical Data Interchange Standards Consortium; 21 CFR Part 11: Title 21 Code of Federal Regulations Part 11 (Electronic Records and Electronic Signatures); GI: Gastrointestinal; FDA: Food and Drug Administration; EMA: European Medicines Agency.

Explore how oomnia supports gastroenterology trials

Request a demo

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