

CASE STUDY

Clario simplifies complex eCOA and imaging GI study with single-vendor solution

Scientific expertise drove high-quality data in an ulcerative colitis study

The challenge

Assessing disease severity in ulcerative colitis trials is complex, and ensuring standardized, compliant data collection and seamless integration across eCOA and imaging components is challenging.

Specific challenges include the following:

- Maintaining motivation and compliance among participants during long, burdensome trials
- Achieving consistent endoscopic image analysis, which can be affected by reader score subjectivity and variable image quality from sites
- Ensuring a coordinated approach between eCOA and imaging data collection strategies, which recognizes interdependencies

A single-vendor approach with an integrated, robust eCOA and imaging solution is a key advantage.

Situation

A European sponsor was performing a three-year ulcerative colitis study with over 300 participants.

This study took place in sites across North and South America, Europe and APAC.

Clario was engaged to collect both remote and in-clinic eCOA and endoscopy imaging primary endpoint data. The data collected was used to assess drug efficacy and for participant eligibility.

Summary

- Three-year global ulcerative colitis study for European sponsor
- Remote and in-clinic eCOA and endoscopy imaging data collection performed by Clario
- Success driven by Clario's single-partner solution, expert scientific support and ability to collect and integrate complex data



Clario ulcerative colitis experience

-  **300+ UC trials** (Phases I-IV)
-  **Key opinion leader**
Dr. Daniel Mishkin (Imaging)
-  **Subject matter experts**
Bryan McDowell MSc, MBA (eCOA)
Marcela Vieira, MD (Imaging)

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Clario solution

Clario provided an integrated eCOA and imaging solution to simplify data collection, integration and reporting for the sponsor.

Clario's consultative, science-led approach included the following:

- eDiary with alerts and engagement tools
- Endoscopic video image acquisition, QC and centralized image analysis
- Site training and 24/7 multilingual support
- Integrated Mayo score data and trial oversight in a single portal



Impact

Study complexity simplified for sponsor

- Data collection, integration and reporting from a single partner

Regulatory-compliant clinical data

- Standardized, compliant data thanks to Clario's high-quality standards, processes and devices for data collection

Participant burden minimized

- Minimal burdensome assessments and deployment of a user-friendly, intuitive app with built-in engagement features by Clario

Clario's success factors

Clario's expert-led approach involved:



Single-partner solution

- Standardized, seamless data integration to minimize sponsor burden
- Real-time visibility of Mayo score and trial progress for sites and sponsor on a single portal



Expert UC-specific scientific support

- Expert coordinated team of eCOA and imaging scientists, gastroenterologists and solution design architects
- Guidance for the entire study lifecycle including protocol and diary design, image QC and centralized reading
- Coordinated approach to eCOA and imaging data collection including recognition of interdependencies



Robust, standardized data collection

- Science-led digital eCOA solution with alerts to simplify participation, drive compliance and ensure high-quality data
- High-quality standards and processes for standardized endoscopy video acquisition, QC, site training and centralized analysis

Our team of experts is ready for your questions about your next eCOA and imaging clinical trial. To contact us, go to clario.com or email info@clario.com

Clario is a leading provider of endpoint data solutions to the clinical trials industry, generating high-quality clinical evidence for life sciences companies. We offer comprehensive evidence-generation solutions that combine medical imaging, eCOA, precision motion, cardiac and respiratory endpoints.