

Clario eCOA Science

Optimize your outcome assessments

Support throughout the study lifecycle

Partner with Clario's eCOA Science team to unlock richer evidence by optimizing your outcome assessments and data capture methodologies for your trial. Our team consists of highly experienced scientists, clinicians and statisticians. We are involved throughout the study lifecycle, ensuring:

- Protocols and study designs contain the most suitable outcome assessments and data collection methodologies.
- Data is of optimal quality and regulatory-compliant.
- Participant-centric solutions deliver high-quality data, both remotely and at study visits.

Clinical development program

- Early-stage support guides your clinical development program.
- The protocol review includes recommendations for assessments, endpoint selection, eDiary design, drug differentiation strategy and more.

Study design

- Device recommendations enhance participant engagement and compliance and streamline site workflows to reduce burden and improve protocol adherence.

Study start-up and conduct

- Tailored participant and rater training programs ensure all raters collecting endpoint data are qualified and trained in standardized approaches to administration and scoring.
- Data analytics, monitoring, independent review and independent ratings help ensure ongoing clinical and scientific oversight of key endpoints, providing timely feedback and recalibration when necessary.
- A specialized eCOA Clinical Scientist supports and/or designs and builds complex clinician-rated measures.

eCOA expertise

60+
scientists

250+
qualified and trained clinician
raters and reviewers

20+
industry-recognized key
opinion leaders (KOLs)

Therapeutic areas and key indications

Our team is made up of specialists across the following therapeutic areas and key indications (including but not limited to):

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|--------------------------------|-----------------------|
| ■ Neuroscience | ■ Women's Health |
| ■ Oncology | ■ Infectious Diseases |
| ■ Dermatology | ■ Pain/Migraine |
| ■ Immunology/Inflammation | ■ Hematology |
| ■ Metabolic/Endocrine | ■ Seizures |
| ■ Respiratory | ■ Cardiovascular |
| ■ Gastrointestinal | ■ Rare Diseases |
| ■ Dementias | ■ Psychiatry |
| ■ Neurodevelopmental Disorders | |

Services delivered by our science team

Science services	Why this is important
Rater training	<ul style="list-style-type: none">Standardizes clinician scoring and interpretation across sites, reducing variability, rater drift and noise in clinician-reported endpointsEnsures data entry only by trained and qualified raters
Independent rating	<ul style="list-style-type: none">Uses blinded central raters to improve administration and scoring consistency, enhance signal detection, reduce site burden and keep endpoint assessments on schedule
Independent review (IR/IREV)/ central monitoring (CM)	<ul style="list-style-type: none">Continuously evaluates and tracks rater and site performance, detecting drift early and enabling targeted remediation to protect endpoint reliability
Data analytics	<ul style="list-style-type: none">Delivers near real-time insight into clinical and operational trends, enabling faster decisions, proactive risk management and stronger data monitoring for regulators
Participant and caregiver training	<ul style="list-style-type: none">Builds confidence and correct use of eCOA tools, improving completion rates and data accuracy and reducing avoidable protocol deviations
eDiary design and modality consultation	<ul style="list-style-type: none">Helps turn complex requirements into intuitive eDiaries that are ALCOA-compliant, low burden and easy to use across devices, boosting data quality and adherence
Cognitive debriefing/usability testing (CD/UT)	<ul style="list-style-type: none">Confirms participants understand and can use instruments as intended, strengthening PRO validity and supporting regulatory acceptance of your COA strategy
Expert screen review	<ul style="list-style-type: none">Verifies that paper-to-eCOA or mixed-mode transitions preserve content, scoring and comparability, protecting measurement integrity and regulatory defensibility
Instrument selection and protocol input	<ul style="list-style-type: none">Matches the right validated COAs to your population and objectives, improving sensitivity, protocol clarity and site compliance from the start
Endpoint strategy and development	<ul style="list-style-type: none">Ensures endpoints are clinically meaningful, evidence-based and aligned with FDA/EMA expectations, reducing regulatory risk and rework later in development

Proven, global partner

Clario focuses on what is important to your study, capturing the critical eCOA endpoint data you need, at home, at the site or in a hybrid model. The unique combination of our deep scientific expertise, global scale and unparalleled experience enables generation of the richest clinical evidence for your study.

With over 25 years of experience, we are the proven and trusted eCOA partner for more than 6,600 studies, 330,000 sites and 2.9 million participants worldwide.