DATA SHEET

CLARIO.

Optimize trial design, data quality and regulatory strategy with Clario's science experts

Biotechs benefit from the expertise and support of Clario physicians and scientists

Access deep scientific and regulatory expertise

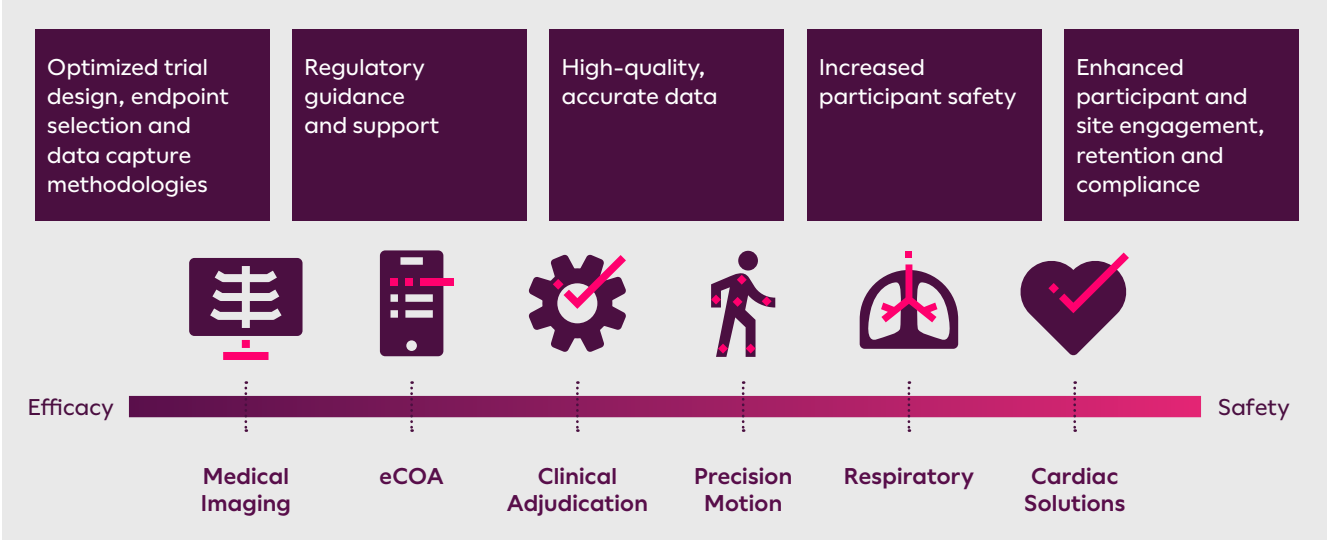
A robust clinical development strategy and an in-depth understanding of requirements across different health authorities are critical to the success of any drug. Clario partners with biotechs of all sizes to provide the deep scientific and regulatory expertise that is often not available in-house.

Early engagement with our science team well ahead of RFP or award is vital.

Optimized trial designs and endpoint selection enhance trial outcomes

Clario's science and medical teams partner with biotechs to ensure the most appropriate clinical endpoint solutions and technologies are incorporated into their trial design, resulting in high-quality, regulatory-compliant data you can trust.

- Recommendations for early-stage clinical strategy
- Regulatory guidance and support (e.g., expert reports and submission briefs) for global regulatory agencies including the FDA, EMA and PMDA
- Targeted efficacy and safety endpoint strategies, tailored to the specific development objectives
- Balancing clinical goals and operational considerations while optimizing participant and site recruitment and retention



DATA SHEET

Scientific support for critical digital endpoint solutions

Clario gives you **direct access** to a team of highly experienced SMEs across the full range of therapeutic areas and indications. Partnering with an organization with a proven track record will support the capture of clinically meaningful, high-quality data for next-step decision-making while minimizing trial delays and accelerating study setup timelines. Our expertise extends across all therapeutic areas. For example,

- Cardiologists support the collection and analysis of early-phase cardiac safety data in support of a QT waiver.
- Imaging scientists provide strategic advice for an optimal read paradigm when using blinded, independent central review of primary endpoint medical imaging data.
- eCOA scientists ensure outcome assessments (such as ePRO) and data capture methodologies are suitable for your patient population when capturing patient- or clinician-reported outcomes.
- Spirometry experts overread respiratory data to identify quality risks and provide real-time insights to site performance.

Reduce the need for a costly internal scientific medical team or high-cost external consultant KOLs.

125
full-time physicians and scientists

All
therapeutic areas

DATA SHEET

Science-led services and support throughout the study lifecycle

Clario's team of physicians and scientists provide comprehensive support throughout all phases of clinical development.

Early engagement with our team enables biotechs to integrate exploratory endpoints in early-phase studies, extracting further differentiated value in early development to accurately inform endpoint selection in subsequent pivotal studies.

Outcome assessments/ endpoint strategy consultation	Early-stage support to guide your clinical development program: ■ Gap analysis and instrument identification ■ Supporting the choice of primary/secondary endpoints	■ Assessment on non-clinical cardiac safety data to help inform design of first-in-human study
Protocol development	Protocol review and recommendations for: ■ Assessments ■ Endpoints ■ Device/modality selection	■ Inclusion, exclusion and stopping criteria ■ Custom instrumented test and/or instruction design
Study design	Recommendations on: ■ Device/modality selection and deployment ■ Type and quantity of data for routine studies	■ In-clinic vs remote assessment ■ Read paradigm ■ Strategies for enhanced participant engagement, retention and compliance
Study start-up and conduct	■ Partcipant, site and rater training ■ Feedback on data quality ■ Independent radiology and oncology data reviews	■ Selection of investigator notifications ■ Data quality monitoring and study oversight
Close-out	■ Review of study outcomes and results ■ Data interpretation ■ Statistical analysis and expert cardiac safety report	■ Rapid database lock ■ Guidance on next development phase/lifecycle opportunities

Regulatory support for communications, health authority and IRB/EC submissions, briefing book and evidence dossier

Make your clinical trials more efficient, effective and engaging for greater regulatory success. To learn more, go to clario.com or email info@clario.com

Clario is a leading provider of endpoint data solutions to the clinical trials industry. For more than 50 years, we have delivered deep scientific expertise and broad endpoint technologies to help transform lives around the world.