DATA SHEET

CLARIO.

Clinical Adjudication Solution

Your trusted partner for a comprehensive Clinical Event Committee solution

Clinical Adjudication plays a key role in determining the efficacy and safety endpoints needed to analyze clinical trial outcomes, which are critical in determining a clinical trial's success.

During this process, an independent clinical event committee (CEC) of experts will review and adjudicate clinical events to classify them against predetermined criteria to evaluate patient safety and clinical efficacy of the drug or device. A centralized clinical adjudication process provides sponsors with a dependable and repeatable process for standardized clinical endpoint data interpretation and analysis and assists with critical-go and no-go decisions during a trial.

Partnering with Clario to manage your clinical adjudication program means you will have a **dedicated project management team** and access to our **global network of clinical experts** to support your trial anywhere in the world. At the core is our **comprehensive, web-based platform** that ensures the accuracy, transparency, and compliance you need every step of the way.

5400+
Sites

12,000+
Users

60+
Countries

70+
Rescue studies

Comprehensive web-based platform with real-time results enabling you to make critical decisions for your study.

Enforce compliance, security and protect patient privacy

- **Automatically redact** sensitive patient identifiers from source documents and DICOM with Redact.AI
- **Manual oversight** via a quality control team that inspects every image and document for proper redaction before they are submitted
- **Complete security and compliance** with audit trials, multi-factor authentication (MFA) and One-Time Passwords (OTP)

Minimize costs and delays and improve efficiencies

- **Easy upload** of source documents, DICOM images, videos, photos, and ECGs
- **Reduce manual errors** and costs with automatic routing and de-identification
- **Automate workflows** incorporating source documents, eCRFs and reports
- **Trigger on-time action** by users with automated email and SMS notifications
- **Integrate easily** with 3rd party EDCs to scan data, enabling the triggering of events
- **Preferred MedDRA term scanning** of EDC database for ease of event notification

Complete visibility and transparency

- **Real-time online access** to adjudication results and data reports
- **Data transparency and tracking** with customizable reports and query management
- **Integrates** easily with 3rd-party applications, including Electronic Data Capture (EDC) and IRT systems
- **Online query management** for all source document types for ease of use for sites and sponsors

Reduce workflow burden, save time and costs with Redact.AI

Redact.AI uses a combination of AI and machine learning to automatically redact sensitive patient identifiers from source documents and DICOM images.

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Clario's Clinical Adjudication platform is fully compliant with multi-national regulations and 21 CFR Part 11, HIPPA and EU GDPR requirements.

Data management and integration engagement team

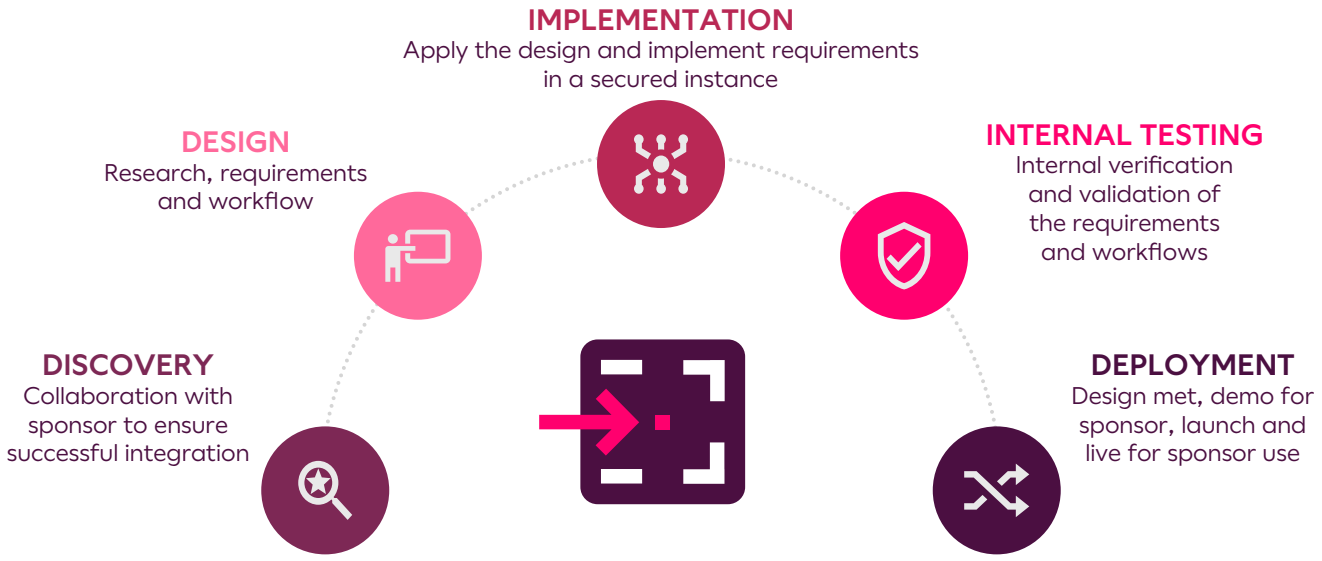
Clario is responsible for authoring the integration specification. Our integrations team will document systems, APIs, workflows, and data exchanged. We are responsible for configuring the integration within the platform and providing practical feedback on the Integration Specification (IS).

Deep clinical domain expertise when it matters most

Our vast global network of medical experts specializes in specific clinical trial endpoint therapeutic areas, including (but not limited to) pulmonology, cardiovascular, oncology, gastroenterology, musculoskeletal and neuroscience.

Almost 90% of clinical adjudication users agreed Clinical adjudication provides value to clinical trials by using unbiased experts to evaluate a drug or device against predetermined events. This helps establish patient safety and clinical efficacy.

— BioPharma Dive and StudioID Industry Survey



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Partners you can trust to manage your program

Clario is responsible for authoring the integration Collaborative project plans are critical success factors in effectively meeting timelines and deliverables. We partner with you from day one and support your program through the end of the study. We provide:

- Experienced project managers assigned to your project who can facilitate global trials at the country level with localized language support
- A team to assist with adjudicator selection and committee management
- Expert guidance on charter design by our veteran adjudication specialists and clinicians
- Nurses and medical writers who can work with project managers to ensure your study is consistent with charter requirements
- Resources who can manage queries and committee member worklists, as well as coordinate the CEC meetings (globally) for remote collaboration to ensure timely consensus

Clinical nurse reviewers

Clinical expertise extends to clinical nurse reviewers (CNRs) who serve in a quality control capacity during the case review workflow, making sure the "story" is in the source documents before it is shared with the CEC for analysis. The CNRs:

- Save the committee time and provides an extra layer of clinical oversight to make sure committee members have all the information required to make an informed decision
- Are key to successful adjudication as they are responsible for all medical content reviews in the dossiers
- Provide an additional layer of quality control to confirm the deidentification of protected health information, eliminate bias that may be introduced via source documents, and certify the study arm is not revealed

Our team of program and project managers has over 100 years of cumulative experience in clinical trial adjudication.

Clario's Clinical Adjudication Solution combines the people and technology you need to overcome the challenges associated with data collection, de-identification, project management, and 3rd-party adjudication platforms.

The award-winning Clario Clinical Adjudication Solution is the fastest-growing adjudication solution in the industry. Our proven combination of project management, medical expertise, and advanced, cloud-based technology is why we have been a trusted partner for more than 70 rescue studies.

Discover more at clario.com
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