Clinical Ink®
Confident Decisions, Faster

Introduction to eLAS™

eLAS (Electronic Lupus Assessment Suite) for SLE Clinical Trials

Clinical Ink has developed a unique offering — the electronic Lupus Assessment Suite (eLAS™) to address fundamental challenges impacting systemic lupus erythematosus (SLE) studies and the integrity of the study endpoints.

eLAS is a therapeutic-specific application of Clinical Ink's Lumenis™. Unlike other applications that simply offer stand-alone electronic versions of questionnaires, eLAS features a fully integrated suite of SLE disease assessment questionnaires, physical assessment, tender/swollen joint count, PGA, and summary forms.

Rather than having to reenter the same data on multiple disease assessments, eLAS allows the investigator to enter data once; the system auto-populates the appropriate fields across the required assessments, reducing time and eliminating errors. The system also ensures that adequate, relevant documentation is in place to support the investigator's findings and disease assessment scale scoring, and it provides immediate access to the data for sponsor/CRO medical data review and adjudication teams for pre-randomization review and visit analysis.

Central Challenges of Lupus SLE Studies

The eLAS solution consists of the core set of SLE disease assessment scales that are consistently deployed in Phase II. The SLE disease assessments included in eLAS are the British Isles Lupus Activity Group (BILAG), SLE Disease Activity Index (SLEDAI), and Cutaneous Lupus Erythematosus Disease Area and Severity Index (CLASI). These assessments are not part of routine lupus patient care and assessment; consequently, investigators, even if they are experienced rheumatologists or even lupus investigators, tend to make grading and scoring errors and fail to document their findings adequately. Given the complexity of the core assessments, the atypical documentation requirements (for a practicing rheumatologist), and the need for repetitive data entry, lupus SLE studies tend to share six common problems:

- Insufficient understanding to properly complete disease assessments
- Insufficient documentation to support scores, grades, and queries
- Time lag between visit completion and data transcription, and between LPLV and database lock
- High number of queries
- Complex, protocol-specific medication rules requiring near real-time review to ensure safety
- SLE disease assessments that are sensitive to small changes and data variability, obscuring ability to detect disease activity improvement

eLAS was purpose-built to address all of these problems.

How Does eLAS Address SLE Challenges?

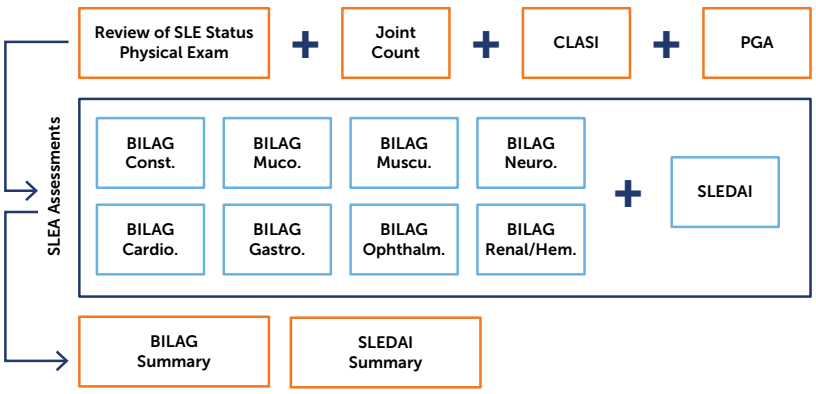
Clinical Ink's goal was to utilize the capabilities of Lumenis to dramatically improve the conduct and execution of lupus SLE studies. Moreover, our objective was to follow the natural site workflow so that eLAS would be as intuitive and efficient as possible. We set out to integrate the core disease assessments used in SLE studies with the required ancillary information such as swollen/tender joint counts, lab data, and the Physician Global Assessment.

In a traditional SLE study, the patient visit begins with a physical examination and a review of disease status. Abnormalities related to lupus or changes to a preexisting lupus finding are documented in paper copies of the appropriate domain-specific BILAG form; some of the data is reentered into the SLEDAI and CLASI forms and finally entered again in to the three summary forms, prior to being transcribed into the study EDC.

To further complicate matters, findings from the current visit must always be viewed in light of the previous visit in order to detect and note changes to the patient's symptoms, and scored in accordance with scoring guidelines, which are in separate documents.

Simply making stand-alone electronic versions of these SLE disease assessments does not solve the problem of duplicative data entry and associated errors/queries and lost productivity. By incorporating the disease assessment scales and scoring guidelines into a suite of integrated electronic forms specific to the SLE disease assessments, eLAS allows the investigator to see pertinent data from previous visits and enter the current data once.

Figure 1: eLAS Data Flow



Just like in a traditional lupus visit, the patient visit starts with the physical assessment. In eLAS, this form drives all the data flow (Figure 1), leveraging over 6,500 cross-form and cross-visit data integrations. Changes can be made to the physical assessment form at any time and the updated data flows through all the necessary forms, updating scores and grades as required. Rather than forcing the investigator to search through the assessments, looking for which domain requires additional documentation and searching for which page to complete, eLAS shows the investigator which BILAG domain assessment to open and automatically locks the sections that do not require completion (Figure 2). Hyperlinks jump the investigator directly to the sections needing documentation, skipping sections that are not relevant for the patient. Required fields are highlighted and if data entered is out of range or otherwise incorrect, the fields remain highlighted, letting the investigator know that something is incorrect at the moment of data entry.

Catching errors during data entry eliminates a substantial number of queries and results in higher-quality data from the start. Edit checks are programmed against both current data and data from previous visits, and scoring guidelines are available on the tablet. eLAS guides the investigator through the completion of all necessary assessments, ensuring that errors are minimized.

High-quality data and documentation are useful only insofar as the CRO/sponsor has quick access to it. Traditionally, data must be transcribed into an EDC system before the sponsor can see it, and the supporting documentation can only be viewed when monitors visit the sites. Transcription results in lag time between patient visit and access to the data, higher query rates, and the need for source data verification.

eLAS features near real-time access to the full range of study documents and data. As soon as the patient leaves the examining room and his/her chart is uploaded, the entire study team has access to the complete chart (Figure 3). The data is encrypted, then transmitted to the Clinical Ink servers where it is displayed in the Insight portal. Here, CRO/sponsor medical data review and adjudication teams have immediate access to the core assessments and all supporting data, including handwritten notes, for pre-randomization eligibility review.

This enables earlier ongoing review and validation of the response scoring and reduces the delay in response generation and resolution experienced with paper scales transcribed into an EDC-based solution.

The queries are raised and resolved entirely within the system. CRAs, medical data review, and adjudication team members review the eLAS assessments and can query fields, forms, or subjects (Figure 4). The site is automatically notified when a query is created. Site users are then able to amend data on the tablet and, if no change is required, respond to open queries via the Insight portal.

Figure 2: Cross-Visit Data Integration Guides BILAG Completion

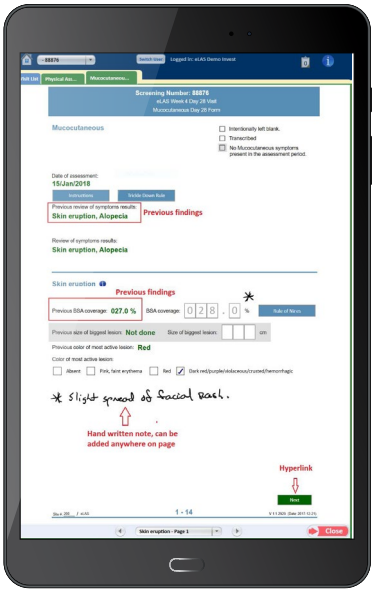


Figure 3: Data Flow

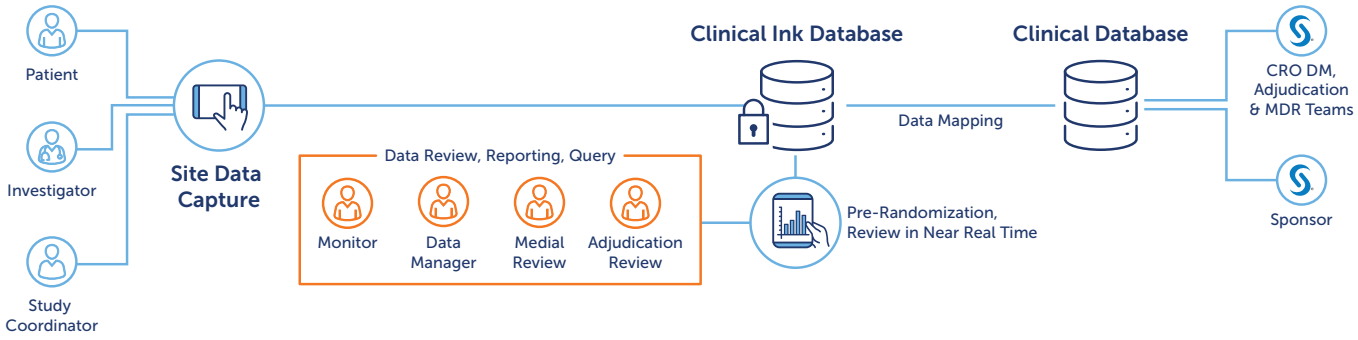
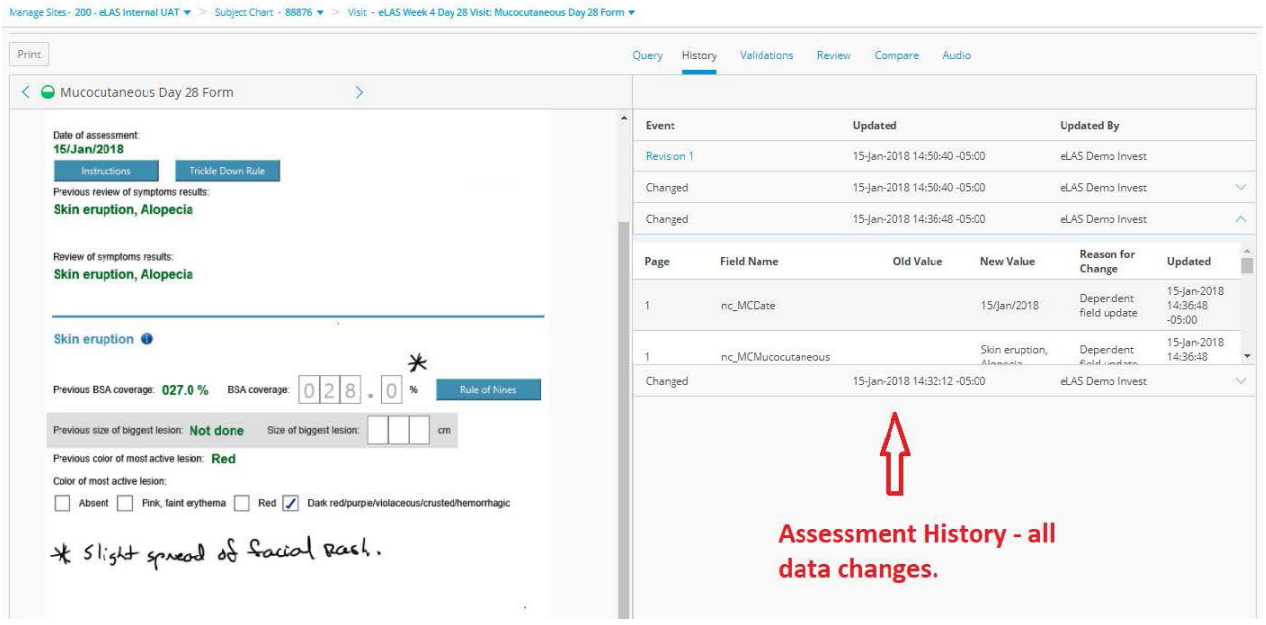


Figure 4: Insight Portal for Medical Data Review and Query Management



Site-Based ePRO Is Integrated Into eLAS

Lumenis offers an integrated solution that can collect clinician-administered SLE disease assessments (via eLAS), clinician-reported outcomes (ClinRo assessments), and any site-based patient reported outcomes (ePRO). In the latter case, the patient enters a "patient mode" where access to the system is limited to the specific instruments that should be completed by the patient, and a patient PIN code is created. This ensures patient-collected data meets ALCOA (Attributable, Legible, Contemporaneous, Original, Accurate) standards for excellence in data quality and integrity and provides sites with a complete regulatory-compliant electronic audit trail at study close for convenient storage and access. Further, Lumenis is validated for compliance with FDA Regulation 21 CFR Part 11 governing software used in clinical trials.

Lumenis is highly flexible:

- Forms (instruments, assessments, eSource forms) can be opened as needed and saved incomplete, e.g., when laboratory data is pending
- Access to assessments and specific functions is controlled by user role
- Handwritten "digital-ink" notes can be added anywhere they are needed to provide context or additional information
- All data can be easily modified, during and after the initial session, with all changes being captured in a robust audit trail
- Charts can be opened on any tablet, regardless of where there were initially created
- Tablets are assigned to sites, not studies or site ID numbers, so single tablets can be used to access charts from multiple studies via a simple, single sign-on

Training

Clinical Ink offers an integrated set of training modalities, all designed to provide users with the skills and knowledge required to take full advantage of eLAS.

The mix of training modalities include:

- Online training via Clinical Ink University
- Clinical Ink application training
- eLAS training (completing forms, navigation)
- Disease activity overview
- IM training (live, face-to-face, hands-on tablet training) for site and CRO/sponsor staff
- Web-based, targeted trainings (individual sites, group of sites, etc.)
- eLAS user guide (PDF)

Clinical Ink, a global clinical technology company, offers data certainty from source to submission. Our eSource clinical technology and configurable ePRO and eCOA modules — a suite of solutions for capturing and integrating electronic data from sites, clinicians, and patients at its source — naturally enhance your clinical trial workflow by reducing manual labor, providing anytime, anywhere data access, and saving resources as your trials progress. Accelerate the completion of key clinical development milestones in your study and confidently manage your trial's critical decisions with our flexible menu of collaborative services, remote monitoring support, and a complete, real-time view of your trial.