Clinical Ink®
Confident Decisions, Faster

The Lunexis™ eSource Direct Data Capture Solution

Save Time, Produce Cleaner Data, and Build Confidence in Your Study Conduct

Enter Data Points into the DDC Tool as They Are Collected

Eliminate the Transcription Step and Edit Checks That EDC Requires

The Clinical Ink interconnected Lunexis eSource ecosystem includes clinical outcome assessments (eCOA), patient-reported outcomes (ePRO – provisioned and BYOD), and eConsent. It also encompasses direct data capture (DDC) for other types of information collected during a clinical trial such as vital signs, physical exam, medical history, and concomitant medications, to name a few. All these elements can work independently or synergistically, as part of a complete system to facilitate your study.

As the pioneers in eSource DDC, Clinical Ink is uniquely positioned to clarify the important differences between DDC and EDC. In contrast with standard EDC setups, DDC benefits include:

- Capturing source data at the moment of inception
- Enabling clean, digitized data to be immediately visible to the research team
- Eliminating time-consuming and error-prone transcription steps and edit checks
- Collecting audio, video and photographs that are embedded with the data
- Facilitating success at NDA filing by promoting correct study conduct and documentation with purpose-built, strategically designed workflows
- Increasing patient engagement

Your Questions, Answered

Are There Any Regulatory Concerns with an Approach Like This?

Simply put, no. These references will set your mind at ease:

- **August 2010 – EMA**
  Reflection paper on expectations for electronic source data and data transcribed to electronic data collection tools in clinical trials
- **September 2013 – FDA**
  Guidance: Electronic Source Data in Clinical Investigations
- **July 2019 – EMA**
  Qualification opinion on eSource Direct Data Capture (DDC)

What About Integration with an EDC System? How Do I Query, Review, and Clean My Data?

There is no need for electronic data capture (EDC). Our Lunexis eSource ecosystem takes its place with configurable, clinical modules: *Direct Data Capture*, *eCOA*, *ePRO+*, and *eConsent*. DDC can capture sources EDC cannot: audio, video, photos, handwritten notes — and anything you can scan or image. A single application consolidates everything from all four modules into one data set, cleaned during the moment that matters (the patient visit), and uploaded to the portal in real time, ready to be reviewed remotely. No paper, no transcription, no source document verification (SDV).

What If I Am Not Sure About Internet Connectivity? What Options Should I Consider When Looking for Solutions That Give Me the Ability to Carry Out Decentralized, Home-Based or Hybrid Studies?

Because they are electronic and tablet-based, DDC systems are ideally suited for highly mobile data collection in ambulatory centers, remote medical locations, or patients' homes. Devices at these sites can function independently and optimize throughput by facilitating proper execution through well-designed workflows and edit checks. Then, as soon as the internet can be accessed, the data can be uploaded to the web for review by the broader study team.

What Do You Do About Existing Medical Records?

When you implement a DDC system, pre-existing information in the paper or electronic medical record, PRO record, or elsewhere may need to be included. At the first visit, historical information such as medical history, laboratory, or common medication data may need to be transcribed into the DDC tool – the same way it would need to be transcribed into an EDC system. Data collected thereafter will be entered directly into the DDC electronic research record. These data, once de-identified, can be scanned and uploaded to the Lunexis platform to allow for remote SDV to be performed for any data that might need to be transcribed.

Lunexis

The Lunexis platform makes it easy to deploy an integrated, convenient eSource solution that provides anytime, anywhere access to your study data. We deliver more than fast, clean data — we deliver confidence. Not only are your sites and patients assured of an easier experience, but you can be certain that your patients are more compliant and engaged and that your protocol is executed correctly. Expect a better study experience through our experienced project support services and customized solutions for specific therapeutic areas, including lupus, gastrointestinal, central nervous system, infectious disease, dermatology, oncology, and many others. Additionally, we have a vast virtual toolkit of solutions, technology, and industry guidance to support your objectives, whether your goal is to decrease patient visits by one, or eliminate them completely.

Start your most complex studies with confidence — implement Lunexis to save time and effort while ensuring data quality from the inception.

Reach Out to Our Experts >

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.