eSource: 6 Steps to Understanding

There's a lot of confusion surrounding eSource. What is it? How is it used? What's wrong with the way I've been recording my data since 2007? Here, we aim to clear the muddied waters.

1. Source documentation is the fountainhead of data

Simply put, source data is the initial data recording. It might be a digital thermometer reading, an electronic medical record (EMR) entry, or an ECG. It might be a paper form or an electronic patient-reported outcomes (ePRO) entry. It might even be the back of an envelope.

In clinical research, where and how new data is recorded matters. The decision has regulatory ramifications in terms of how the data is cared for, how long it must be retained, and who has access to it. Technically, as you know, a blood pressure recorded on the back of an envelope triggers an audit trail that will need to be followed throughout the trial to ensure data integrity. That envelope will then need be preserved for years after the clinical trial ends, the principal investigator (PI) will be legally responsible for safeguarding it, and so on.

2. eSource is the digitization of source data

While the majority of research data still begins on paper, digital source data capture is rapidly taking its place. For one thing, a digital audit trail is much simpler to maintain than a paper audit trail. Further, optimizing source data accuracy only makes sense; if the fountainhead is contaminated, measures to protect the purity of the data downstream will be meaningless.

The goal of eSource, then, is to save time and effort while ensuring the highest possible data quality and regulatory compliance by protecting data from its inception. It also allows researchers immediate access to the digitized data.

3. eSource may include a variety of methodologies

At Clinical Ink, we talk about an interconnected eSource Ecosystem — Lumenis™. This system includes digital clinical outcome assessments (eCOA), ePRO, and eConsent forms. It also encompasses direct data capture (DDC) for other types of information collected during a clinical trial, such as vital signs, ECG, and blood or urine

screens. These data points are entered into the DDC tool in real time, as they are collected. By eliminating the need for later transcription, this direct entry saves time and reduces errors.

While DDC may seem like standard electronic data capture (EDC), they are different. In an EDC trial (the vast majority of trials), data is initially recorded in an electronic medical record (EMR) or in a paper research chart that includes protocol-specific information: diaries, questionnaires, and extra physical exam notations. Information from both the EMR and paper record is then *transcribed* into the EDC tool. It is very rare that data is entered *directly* into an EDC tool. It is this time-consuming, error-prone, paper-record transcription step that DDC and other eSource applications and processes eliminate.

ePRO captures data directly from patients, replacing patient paper diaries that would then have to be transcribed into an electronic system. Similarly, eCOA questionnaires capture data directly from clinicians, replacing an assortment of specific forms created for a variety of research purposes that would also need to be transcribed. With DDC covering the rest of the data typically recorded on paper, Lumenis makes your entire clinical site eSource; everything is contained within the electronic research chart and the EMR.

4. Experienced implementation of eSource supports your protocol in ways EDC systems can't

The ultimate goal of any clinical trial is to prove the efficacy and safety of a drug. The protocol establishes a hypothesis and when and how to prove or disprove it. The protocol must then be executed according to the data collection methodology it specifies in minute detail.

What are the possible pitfalls? Here is the 2018 FDA list of common clinical investigator observations:

- Failure to conduct an investigation in accordance with the signed investigator statement or agreement/ investigational plan/applicable regulations
- Inadequate or inaccurate case histories
- Investigator's subject records inadequate
- Inadequate drug/device disposition records
- Failure to obtain informed consent in accordance with Part 50

Many findings revolve around improper or insufficient protocol execution and documentation. One benefit of Clinical Ink's Lumenis eSource Ecosystem is that the DDC applications are custom-designed to ensure procedures are followed correctly. We are, at this moment, helping clients perform 116 studies in 50 countries, and our team has 14 years of experience working in clinical trials. We are experts in site workflow and have designed forms to facilitate research projects in a wide variety of therapeutic areas. We work with sponsor and

CRO data management and Clinops teams to help improve protocol execution by building the requirements into our DDC screens.

Required fields, timers, and so on help ensure investigator teams follow the protocol with precision, leading to cleaner data and the documentation regulators require. The guides and fail-safes our experienced personnel design are extremely valuable.

The attrition rate for principal investigators is so high that about half of studies are performed by first-time investigators. They might be experienced physicians, but even the most experienced investigator can make mistakes in protocol conduct and documentation. The immediate feedback inherent in Clinical Ink custom DDC designs improves clinical trial execution, produces cleaner data, and helps ensure that documentation complies with regulations.

5. Our eSource Ecosystem builds confidence and simplifies conduct for all stakeholders

Patients

The patient dropout rate in clinical trials is high: 18-21% or more, depending on the trial. Many people eventually become disengaged, start missing doses or other trial activities, and simply quit. However, immediate feedback from well-designed patient interfaces can provide the encouragement and reinforcement patients need to stay engaged long enough to finish the study.

Investigative sites

Basing investigative site operations on an eSource rather than an EDC system disburdens the site and eases compliance with various regulations and documentation requirements. Time savings are significant:

- Eliminating transcription regains 20% of the time a site typically spends on clinical trial activities
- Well-implemented eSource eliminates 25% of the queries, which require time to investigate and resolve
- Entering data directly into an electronic tool saves 19 hours previously spent creating paper sources

Sponsors

Similarly, eSource improves data quality and creates operational efficiencies for sponsors. In our earlier blog on the EMA's support of eSource, we reference a Novartis trial that utilized our Lumenis eSource platform, in which:

- The time to data availability dropped sixfold
- The number of data points that remained unchanged throughout the study increased 7%, indicating fewer data or monitoring queries
- The time to resolve data queries dropped by more than 50%

While these figures are significant, they only tell part of the story. What leads to even more confidence is experience. As the pioneers in this field, the Clinical Ink team has helped thousands of sites conduct clinical trials, including many established Phase 3 trials. The experience and leadership of our project managers and program designer — and the sophisticated systems we have developed — mean clients can confidently rely on us to help track everything with operational rigor and efficiency.

Furthermore, a study does not need to entail complex documentation to benefit from our Lumenis eSource Ecosystem. Even a simple study that doesn't require patient diaries (ePRO) or complex clinical questionnaires (eCOA) can benefit from Lumenis for DDC. Our specially designed processes, from direct source data entry to customized investigator input screens, enhance data quality and ensure proper protocol adherence from trial start to finish.

6. A well-supported eSource Ecosystem not only saves time, but produces cleaner data and builds confidence in correct study conduct

Lumenis, our clear and connected eSource Ecosystem, includes DDC processes in addition to eCOA, ePRO, and eConsent functions. Compared with standard EDC setups, the benefits of this technology platform and the delivery capabilities of our experienced team of clinical research and study workflow experts include:

- Capturing source data at the moment of inception
- Making high quality, digitized data immediately visible to the research team
- Eliminating time-consuming and error-prone transcription steps
- Facilitating success at NDA filing by promoting correct study conduct and documentation with purpose-built, strategically designed data capture solutions

The Lumenis platform makes it easy to deploy an integrated, convenient eSource solution. 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.

From simple to complex, Lumenis is built to meet the demands of your trial. Start your most complex studies with confidence — implement Lumenis to support well-informed, optimal decisions.

Subscribe To Our Blog To Learn More >

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.