

## CLINICAL INK

# Electronic Source Records (ESR) — What EDC Should Have Been

The single biggest cost driver of late-stage clinical development is the on-site monitoring of paper source documents at the site. Capturing source data on paper, while initially easy, ultimately is costly, error-prone, and time consuming for both sites and sponsors. Eliminating paper source documents will reduce monitoring and data query resolution costs by HALF — while lowering compliance risks.

Nonetheless, paper remains prevalent at sites, even in EDC studies, because of familiarity and a lack of viable alternatives. Clinical Ink has developed the first electronic source record (ESR) to meet FDA, EMEA, HL7, and CDISC standards and guidelines to replace paper source documents with electronic forms — particularly the requirements relating to electronic source *documents* versus source *data*.



### How Does Suresource Work?

Clinical Ink's SureSource™ solution maintains the natural workflow, ease of use, and mobility of a paper chart — everything from “pulling a chart”, capturing handwritten notes & drawings, flexible navigation, and the freedom to work without regard to connectivity — while allowing fast, secure transmission of source documents and data electronically.

**SureSource Tablet** — Investigators and Study Coordinators use a tablet PC instead of paper forms to record patient visit details. The information on the form is converted to data and auto-populates the study database — all the time, effort, and error associated with re-entering data into a CRF is eliminated. Additionally, real-time data validation and “intelligent” forms ensure information is captured completely, accurately, and in exact compliance with the protocol while the patient is still in the room.

**SureSource Portal** — Monitors, sponsors, and site users access a web portal to review electronic source documents remotely as the visits happen in real-time. Source Data Verification (SDV), the

most time consuming and least valuable monitoring activity, is eliminated; there are no discrepancies between the electronic source document and the database. As a consequence, monitors can apply their expertise to review source documents for relevant medical context, safety trends, and protocol compliance rather than wasting effort to identify simple data errors and omissions.

### Benefits

In addition to relieving the work burden on sites, directly quantifiable benefits to sponsors include:

- Eliminate SDV cost and time; up to 50% of monitoring effort is SDV; partial SDV increases risks
- Dramatically reduce queries; 65% of data queries are due to discrepancies with source documents
- Remote real-time site monitoring; more frequent/focused interactions with less on-site travel
- Audit trail of source; dramatically reduce risk of fraud and increase protocol compliance

- Site recruitment enhanced; sites are paid within days for fully validated/reviewed data and use a tool that actually reduces their workload

Patient care also improves as details of clinical research visits can be included as part of the patients' medical record either as an HL7 data export or printed paper copy — all without added work by the site.

Electronic source is the best option to fundamentally alter the business model of clinical development.

The image shows the Clinical Ink logo, which consists of the words "Clinical" and "ink" in a stylized font, with a checkmark inside the letter "i" of "ink". Below the logo is the website address "www.clinicalink.com". At the bottom, the slogan "Keep the Pen. Not the Paper.™" is displayed in a bold, sans-serif font. The entire graphic is set against a light blue background with a white arrow pointing towards the logo.