A Unified Experience in eSource Patient Data Capture and Integration for Sites and Sponsors

Clinical Ink is continuously leveraging our experience and customer feedback to improve processes, enhance operational efficiency, and increase configurability so that our integrated Lunexis™ eSource platform continues to surpass client expectations. This three-blog series will explore some of our ongoing enhancements.

Part II (of III)

How does refining our connected eSource Ecosystem achieve a unified experience for sites and sponsors? It's not just about features — it's about efficiency. In PART I of this series, we explained how this enhanced platform allows users to choose whichever data capture modality they like and switch from one to another at any time. This capability enables users to be efficient and stay engaged. Beyond that, a unified authoring tool simplifies and speeds up implementation by flowing a single authored document onto all the available modalities. Finally, unified reporting makes more data sources visible at the same time than ever before, enabling sites and sponsors to consider data from a variety of sources simultaneously. This refined, comprehensive-yet-flexible eSource data capture and integration platform helps ensure that studies run on time and on budget, delivering the real-time data needed for confident decision-making.

Greater operational speed and efficiency accelerate your study

Lunexis™ is the only purpose-built platform compatible with any trial design. Using this highly configurable eSource ecosystem, sponsors can streamline clinical trials with fast, clean data, deploying technology based on the needs of their protocols, rather than tooling protocols to conform to the limitations of technology. This holistic platform — with enhanced Lunexis ePRO+ and ClinRO+ technologies — empowers sites and patients with an easier, more positive clinical trial experience, collecting cleaner data for timely, crucial decisions. Recent optimizations move studies from protocol to simplified, patient-centric solutions and commercialization in less time.

We've already seen how the freedom to select modalities as needed benefits patients and keeps them engaged better (Part I), but it also benefits the site and the sponsor. For example, say a clinician

walking down a hallway to an exam room needs a mobile interface and grabs a tablet. Later, they might be doing other work at an office desk or at home and prefer to use a desktop to complete eCOA tasks.

Or, when a patient is unable to come to the office for a scheduled visit that was supposed to include an in-office ePRO entry, with a tablet-only system, there is no substitute and the data points would be missed. For a complicated form, smartphones aren't a good interface either, but with mixed-modality capabilities, the patient could use a web-based version of the app. This is also a great solution for very long studies, such as Phase IV, which might continue for years. In many studies, BYOD is an excellent option, but probably not in a decade-long study likely to encounter multiple phone technology upgrades along the way. Instead, the option of switching to a web-based system as needed imparts the necessary longevity to collect data for these long periods. This means enhanced Lunexis eSource technology can be used for virtual or hybrid trials in a wider range of phases and for therapeutic areas, such as oncology, that typically require extended follow-up.

Alongside Lunexis ePRO+, sites and sponsors will also benefit from the enhanced Lunexis ClinRO+ module. This application is now more flexible and easy to use, enabling sites to support a wide range of ClinRO, ObsRO, and PerfO. Together, these tools provide sponsors with a streamlined, patient-centric solution that has the flexibility to customize patient engagement and site interfaces to best support complex trials in any therapeutic area.

Unified authoring tool drives 3x-faster study builds

Lunexis enables sponsors to deploy configurable, mixed-modality ePRO solutions, fast. This is, in large part, thanks to our unified authoring tool, which means teams only need to build an instrument once and the design can be flowed across multiple modalities. A single ePRO design can be implemented on tablet, smartphone, and web interfaces, easily giving patients and site users the freedom to switch back and forth across devices at their convenience, facilitating better compliance and study execution.

While some custom-built ePRO software solutions are slow to deploy and demand too much from busy study teams, unified, simplified authoring makes this powerful, flexible solution different. Clinical Ink project teams and ePRO/eCOA experts quickly design and deploy prototypes for sponsor and CRO design reviews and approvals rapidly. Our authoring tool, employing configuration rather than programming, eliminates almost all coding, and enables deployment with improved efficiency, three times faster than before.

This approach speeds up complex document reviews and facilitates sponsor feedback. Better collaboration between sponsors and project managers smooths user acceptance testing (UAT) and eliminates surprises from the final review. Once approved, each design can be deployed on all relevant modalities with one click. The bottom line is that these efficient study builds enable rapid ePRO deployment as they:

- **Unify authoring:** A single design deploys to web, tablet, and mobile devices
- **Simplify ePRO design:** New questionnaires are easily created or built from templates or often-used elements
- **Speed translation:** Real-time editing and direct translator access lead to faster build times

Once designs are deployed, the next step is to train personnel in their use. We've been doing this for 20 years; we know training can be tedious and that users often have a hard time retaining what they've learned. To plan for this, we've embedded technology for real-time, in-app training. Effective, interactive training through engaging, role-based walk-throughs, knowledge base resources, and live chat simplify and streamline learning to promote efficient use while improving retention. Finally, enhanced user interface services both home and site-based data.

The improved Lunexis site-facing app offers a more expansive view into ePRO data collected both at the site and away from the site. Previously, site personnel looking at a patient chart would only have insight into answers a patient entered during a site visit. To see what a patient entered at home — what tasks were done, what tasks were missed — required running a report.

Now, Lunexis provides quick insight into data collected at both the site and at home. During the patient visit, the clinician can look at a patient's history of task completion and respond to it encouragingly or discuss omissions to ensure compliance goals are met. If additional details are required, a full reporting environment is available as well. With one tool, one moment, and one view, clinicians can access all their data.

As always, with Clinical Ink's eSource technology, data is most frequently entered directly into the digital record during the moment that matters — the patient visit. Not only is this data accessible almost immediately, while corrections can still be made, but it does not require traditional source data validation (SDV) — enabling critical, early decision-making and rapid query resolution while saving time. Enhanced Lunexis deploys questionnaire-compliance summary email alerts for site staff and monitors as well as smartphone push notifications for patients, further promoting complete data collection.

Clinical Ink's enhanced eSource Ecosystem is a comprehensive yet flexible eSource data capture and integration platform that will simplify real-time data collection to provide a continuous workflow to ensure studies run on time and on budget and allow sponsors to make key decisions with confidence.

Learn more about patient and sponsor data integration, enhancements that allow integration with best-in-breed, third-party systems, and the benefits of Clinical Ink therapeutic area-specific libraries.

Read Part III

Understand more about enhancements that allow mixed modality deployment compatible with any trial design.

Read Part I