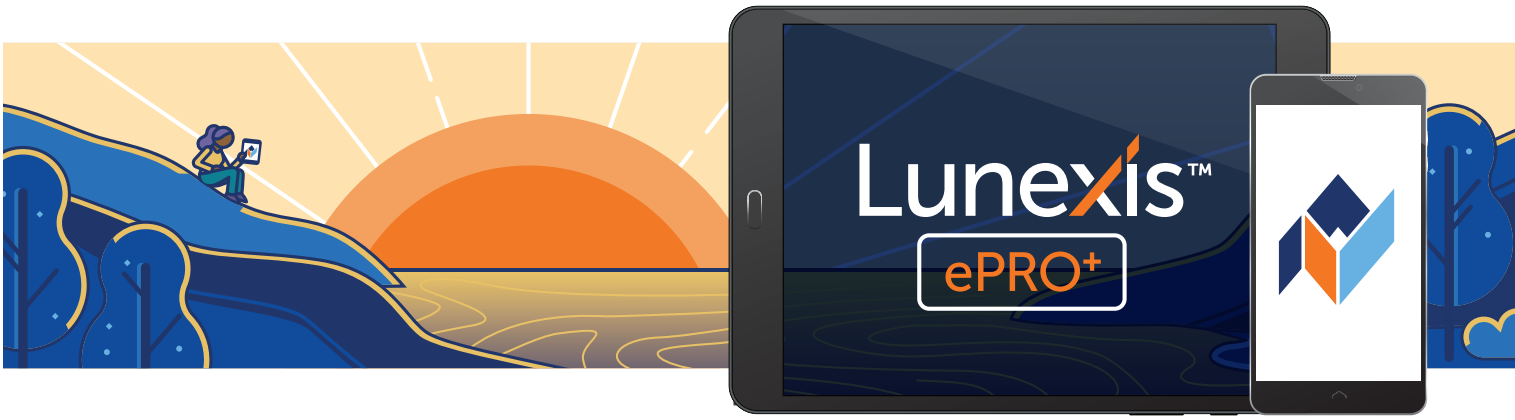
Clinical Ink®
Confident Decisions, Faster

# One Patient Data Capture Application That's Everything to Everyone: The Evolution of Lunexis™ ePRO+




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 III (of III)

In PART II, we talked about the benefits to site users of a combined view into all ePRO+ sources, whether at home or on site. With complete information surrounding patient activities, the research team can be more proactive in monitoring patients and encouraging them to stay engaged and remain compliant.

But the exciting thing is, Lunexis ePRO+ is only a fraction of the story. The **single platform** that supports this aspect of Lunexis ePRO+ will also be enhanced in its support of all the other data input modules. The unified Lunexis+ platform is evolving into a complete, configurable, detailed data capture and reporting environment for sponsors, patients, and site users.

### Lunexis delivers the broadest variety of data in clinical research

The same platform that supports ePRO+ and ClinRO+ will be enhanced to also support eCOA and DDC studies, regardless of complexity. It will also support a patient portal, allowing patients to log in from any computer and access a web app for their ePRO needs.

**One platform beneath the different modalities supports:**

- Home-, site-, and web-based ePRO+
- Sponsor review, query, DCF, and reporting workflows
- Site-based clinician reported data
- ClinRO, eCOA, and DDC

What are the advantages of this unprecedented breadth and variety of data being collected and presented in one place?

As a data manager or monitor, you only need to know how to use one system. You also only need to check data on the one web app because you can go there and access all the data collected through all the above modalities. Further, dealing with a single vendor for everything is a much more streamlined process than having to interact with multiple points of contact and then figuring out whether there's a way your various systems can be connected.

In short, the unified Lunexis+ platform from Clinical Ink delivers the benefits of having one vendor with a single application supporting the full range of your clinical studies:

- Ease of use
- Time savings
- Operational efficiency
- Cost savings

## Customizable dashboards allow users to focus on only the data they need

With robust reporting and data analytics built into the platform, sponsors and CRO users gain valuable insight into the data in real time. Self-serve ad hoc reporting options allow users to easily set up in-depth dashboards that provide immediate view into the data most critical to their job functions. Being able to focus on a real-time, unique perspective of what really matters, sponsors and CRO users save time and ensure they see what they really need to see.

## The single platform provides unique data security benefits

Catastrophic data loss is everyone's nightmare. A unified, single-vendor application with one secure way to access and manage all study data generated by the patient at home via phone or web or generated by the patient or clinicians at the site eliminates chinks in security associated with more open systems. Not having a variety of data scattered about in various systems means that from a security point of view, we can lock the entire platform down far more easily than if the data resided in many different systems.

The reason is that anytime you connect one system to another, you add risk of penetrability. The more vendors you need, and the more separate systems are exchanging data and sharing data, the more opportunity there is for either an error or a malicious attack to occur. With a single, unified platform, it's easy to minimize this type of risk.

Granted, there will occasionally still be third-party, best-of-breed systems that must be incorporated. Lunexis+ platform's API-based integration layer, paired with our in-house expertise, was developed for just these situations. This platform facilitates integrating with other data sources when necessary. Enhancements made to the platform support fast, secure integration with up and downstream sources.

## Experience improves operational speed and efficiency, especially in complex therapeutic specialties

We apply what we've learned while supporting hundreds of study-years of clinical trial conduct to direct our ongoing Lunexis+ enhancements. Recognition of the importance of allowing patients and site users to choose their own modalities, for example, is based on understanding gained in hundreds of clinical trials across a wide range of therapeutic areas from lupus to atopic dermatitis to oncology to GI. Such improvements, grounded in experience and combined with therapeutic-area-specific adjustments, allow for greater operational speed and efficiency.

As each user can set up their own view of data based on what's important for their role, and data is available in real time, everyone has the customized information that they need to continually make confident decisions to keep the trial on track.

## Enhancements for faster research study design

One of Clinical Ink's hallmarks is fast study builds. With Lunexis+ enhancements, they are three times faster. Our configurable Activity Designer allows teams to build all their data capture screens — from the simplest ePRO to the most complex eCOA — in DDC studies via configuration rather than programming. That means that once they've gathered the requirements for the questionnaire, they don't pass them on to an engineering team to program the screens.

Rather, the study build team uses the configurable controls to drag and drop elements on the screen. And rather than programming an edit check, they can just select edit check and select what it should do. Not only is it fast, but anyone can build an ePRO or eCOA questionnaire without a programmer.

Furthermore, the Activity Designer displays the image of the screen on the device you specify, either a phone or the web. So rather than waiting until it deploys to see if it looks right, you know immediately. If it has to go on multiple devices, you can switch views and quickly check them all. This is great for BYOD studies, which are viewed on a variety of different phones.

## Reusability of components can be key in complex therapeutic areas

One more client-driven Lunexis+ enhancement is access to client-specific activity libraries. These libraries allow teams to save the instruments and questionnaires that they've built. In addition, these questionnaires and instruments may be saved with their translations and data mappings for reuse in later studies.

This capability is especially valuable in complex therapeutic areas where instruments and procedures are standard and often reused. While a copyrighted translation will need to be reapproved by the license holder, this is a process Clinical Ink has a lot of experience navigating with our clients. So, for example, having specified for one study which data values map to normal/no action and which map to flag for PI, you can reproduce or simply tweak this setup if you need it again for a future study. This ability to reuse various elements of design saves a lot of time and effort in the long run.

## The configurable Lunexis+ platform: Your enhanced, connected eSource Ecosystem

By continuously leveraging our experience and customer feedback to improve processes, Clinical Ink has developed important enhancements in the form of Lunexis+. Streamline your clinical trials with more than fast, clean data — now gain even greater operational speed and efficiency with the single, unified Lunexis+ platform.

To achieve a better trial experience for everyone, this platform is evolving into a complete, configurable, detailed reporting environment that presents sponsors, patients, and site users with data points they select from an unprecedented range of modalities. Greater operational speed and efficiency, increased configurability, and 3x-faster study builds enable sponsors and CROs to make confident decisions that keep their trials on track.

Sites' and patients' new normal is constantly changing. That's why we've committed to continually enhancing the Lunexis eSource Ecosystem — without trial disruptions.

Imagine a single technology that flexes to support you from protocol development to commercialization. Make it a reality with Clinical Ink.

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

Read Part I

**Learn about enhancements in eSource patient data capture and integration, and how site and sponsor teams are able to view the data through further ongoing enhancements.**

Read Part II

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.