

Virtual Trials

Trust in Experience, Trust in Lunexis™



From Infectious Disease to BYOD, We Set the Bar for Virtual Trials

Pioneers of direct data capture, virtual trials, and fully integrated patient engagement

All science aside, operational issues can be a huge impediment to rapid, safety-conscious, cost-effective research. Implementing a virtual eSource platform wherever it makes sense can make a big difference — and Clinical Ink is the hands-down leader in virtual trials.

Clinical Ink’s Lunexis eSource Ecosystem of configurable, interconnected technologies is ideally suited to virtualize part or all of your trial. With our platform, you follow the data your sites and patients are capturing in real time. Then you make critical decisions — fast.

Whether it’s a hybrid virtual trial or you are eliminating patient visits entirely, your trial will be expedited by our vast technology toolkit. Direct data capture (DDC), bring your own device (BYOD), provisioned electronic patient-reported outcomes (ePRO), electronic clinical outcome assessments (eCOA), timely risk-based management (RBM), eConsent, telemedicine, home health visits, connected devices/wearables, and more can all be implemented and supported to make your data stream and your work flow.

Get on the path to BYOD.
Ask about our successful studies involving 20,000 patients across Phase I-IV+ clinical trials.

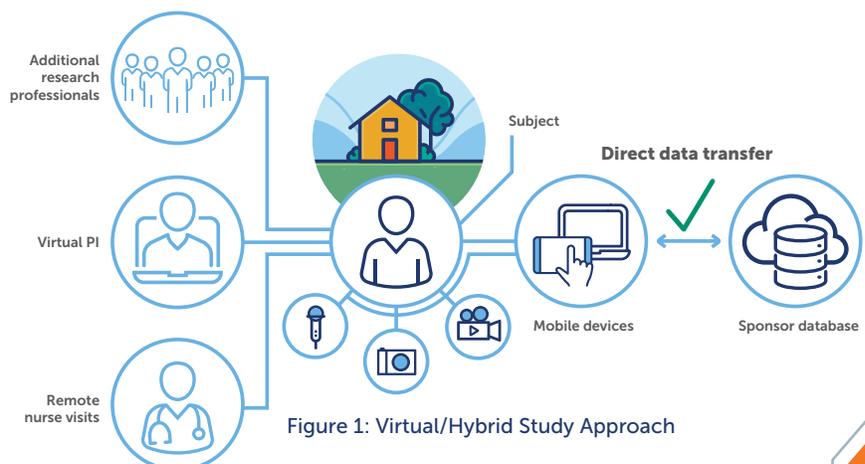


Figure 1: Virtual/Hybrid Study Approach



Better for Sponsors

- Gain immediate access to validated data
- Accelerate recruitment and improve retention
- Cut out monitoring charges for lower costs
- Connect better with productive sites
- Get automated site analytics and reporting
- Speed up database lock
- Know devices/wearables are part of the eSource ecosystem



Better for Sites

- Enter data ONCE!
- Use virtual trial tools to recruit and retain patients
- Validate data as you capture it
- Use a single tool for eCOA and other trial data
- Use a familiar document-based solution
- Connect with patients easily
- Enact secure televisits with direct data capture



Better for Monitors

- Focus on source data review (SDR) instead of source document verification (SDV)
- Travel 70% less, doing all SDR remotely
- Focus on the most important data through guided and targeted SDR
- Review source document audit trails and system logs with ease
- Review home visit data right away

Ebola Case Study

Public health emergency, WHO-mandated timelines

Challenge

Two Ebola vaccine studies

- 9,000 patients, adult and pediatric
- Five northwest African countries
- Six trained, eight untrained sites
- Rapid enrollment (9,000 patients in four months)

Sites overwhelmed by patient volume, workload
Plagued by data transcription errors and time lag

Solution

204 users deploy Clinical Ink eSource DDC including eCOA

- Intuitive, easy to use
- Higher productivity
- No duplicative data entry
- Extensive real-time validations
- Issues quickly identified and resolved
- Learnings shared across teams
- Remote monitoring extensively leveraged

Data available for review within 20 minutes

0.14% manual query rate on over 20 million data points collected

Study accelerated, database lock two months early

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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.