Clinical Ink®
Confident Decisions, Faster

Decentralized Trials

Trust in Experience, Trust in Lumenis™

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

Pioneers of direct data capture and fully integrated patient engagement

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

Clinical Ink's Lumenis™ 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 decentralized 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, and more can all be implemented to make your data stream and your work flow.

Get on the path to BYOD. Ask about our successful studies involving 15,000 patients across Phase I-IV+ clinical trials.

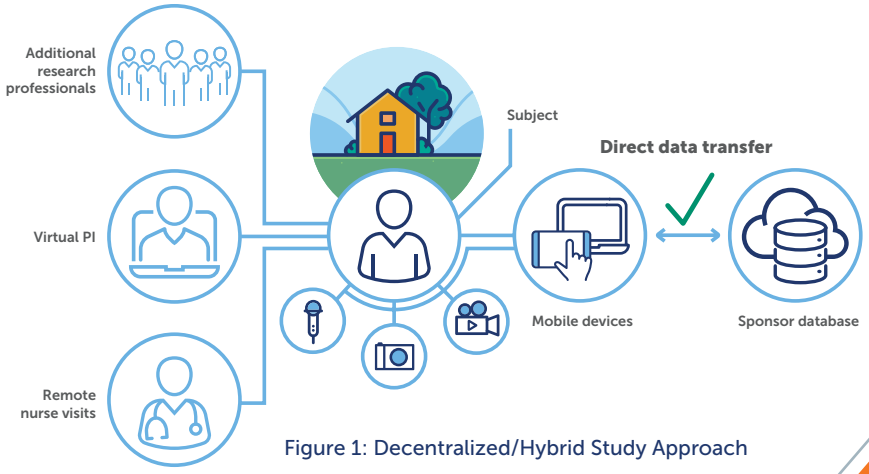

Figure 1: Decentralized/Hybrid Study Approach

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

Better for Sites

- Enter data ONCE!
- Use decentralized 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

Better for Monitors

- Do away with source data verification (SDV)
- Focus on source document review (SDR) instead
- Travel 40% less, doing all SDR remotely
- Focus on the most important data through guided and targeted SDR
- Record source document audit trail with ease

Ebola Case Study

Public health emergency, WHO-mandated timelines

Challenge

2 Ebola vaccine studies

- 6,000 patients, adult and pediatric
- 5 northwest African countries
- 6 trained, 8 untrained sites
- Rapid enrollment (3,000 patients in 4 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

REACH OUT TO OUR EXPERTS >

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.