



An Alternative Source Document Solution for COVID-19 and the Future

Eliminating the need for redacting while providing read-only access

The COVID-19 pandemic has forced the need for remote work and has put an added importance and necessity on remote monitoring of research sites. This has generated conversations about remote work and monitoring after the pandemic is behind us. Many of our customers who are leveraging our platform for regulatory document management have realized a need for a solution for remote source document monitoring as well -- particularly when their current processes and systems aren't meeting their needs. Together, we realized our unique approach to regulatory document management could be applied to source document storage and review as well -- providing a compliant and effective solution in lieu of a separate, purpose-built eSource solution.

THE NECESSARY SOLUTION

Complion's history and dedication is entirely in clinical research. Even with a focus on regulatory documents, we knew our product needed to support HIPAA compliance to keep patients' information safe however it might be included in regulatory work. We also ensure our product supports FDA compliance. Additionally, we have structured our system in such a way that makes document retrieval and review easy and secure. With all of this, we knew we had the foundation our customers needed to create a source document review solution that was easy to use for staff as well as for monitors.

THE KEYS TO OUR SOLUTION

- **Proven.** We have already partnered with customers to implement these solutions. Specifically, one research site in Texas has 11 patient document binders specifically built for remote monitoring. Here's what the regulatory manager at that site had to say:

"... we received positive feedback from a CRA after monitoring remotely using Complion's Source Document Template. The CRA commented it's 'easy to view documents and locate them'. It made her day go by easy and fast!"

- **No need for redaction.** Though other solutions leverage redaction of sensitive data to ensure compliance, our system can enforce read-only access for monitors which supports the same compliance, yet gives simple, total access and eliminates the work involved in redaction.
- **Quick and easy access.** Our system uses data stored together with the documents to make searching and finding these documents easy. That same data is the power behind controlled access plus the simplicity in knowing exactly what a document is and how it is relevant.
- **Enforced consistency through best practices.** Beyond the power of searchability, we also provide completely templated patient document binders -- another simple way of finding each document. This consistency fueled by best practices is what we've learned from partnering directly with sites.

Do you want to spend time doing unnecessary work only to provide your monitors with a lot of files to review and still receive action items because Sponsors or CROs can't find the data they need? Or, would you rather provide a high-quality, remote visit where all the key info can be viewed and know where it is and not worry that a copy has been captured of something that's wrong?

It's not just about the redacting. It's about how much easier the work can be done.

Don't just replicate your bad paper process with a bad digital process. Partner with Complion for a powerful solution that makes regulatory and source document review simple -- from anywhere.

LET'S BECOME YOUR PARTNER. CALL US TODAY.

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