



## **Elligo's COVID-19 Response for Sponsors/CROs: How Elligo Supports Remote Monitoring Visits**

Because Elligo's core model is paperless, supporting remote monitoring visits is easily facilitated. We are powered by our IntElligo Research Stack™ for electronic subject source data collection and Florence Healthcare eBinders for our electronic investigator site file. Both of these systems were built with flexibility in mind and always allow our monitors/CRAs to access our data, remotely, at any time.

### **What's the process for remote monitoring visits?**

As with any monitoring visit, please let our Study Coordinator know when you need to monitor our site, even remotely. They will work with our IntElligo and Florence teams to provide you with appropriate access to the systems for your remote visit.

Source documentation and PDF uploads of subject Informed Consent Forms will be reviewed as required via IntElligo.

Study documentation will be reviewed as required via Florence, including regulatory documents, temperature logs, equipment calibration records, etc.

Elligo also uses webinar/video conferencing technology, which can be used to support discussions or even video walk-throughs, in order to complete remaining monitoring activities as required. For instance, study supply inventories (e.g. lab kits, ECG leads, electrodes and paper, paper scale documents) can be reviewed and investigational product accountability may be performed via video. At the conclusion of monitoring, discussion with the principal investigator can also occur as required. Our conferencing options are Microsoft Teams and Amazon Chime.

If review of facilities is required, either based on monitoring schedule or marked change, we will work with you to provide appropriate documentation (e.g. photographs and descriptions) for your consideration.

Upon completion of the remote monitoring visit, the Study Coordinator will make an entry on the Monitoring Visit Log, denoting the visit was conducted remotely.

## **What if the study I'm monitoring was before IntElligo was implemented and the subject source is managed via paper?**

All active studies at Elligo use IntElligo, even if it's just to track the occurrence of a patient visit. Each legacy study supports a "file upload" of scanned paper source documents. In preparation for a remote monitoring visit, our Study Coordinator will scan the appropriate subject source documents and upload into IntElligo. Then, the monitor/CRA may use IntElligo's CRA Review functionality to review that data. This will not be considered a "certified copy," and original paper source will be retained as required.

If you have any further questions about our processes to support remote monitoring visits, please contact your Study Coordinator and/or your Elligo Project Manager.