

Q&A: External Monitoring

How can we gear up to allow for more remote monitoring - this is a project that we need to do quickly. Is part of the answer Forte eReg implementation?

- Guidance for managing externally-monitored studies during the pandemic:
 - Consider using this time without on-site visits to catch up on any **delayed data entry** and address **query backlog**
 - If remote visits are required for source data verification, define critical source data verification requirements with the monitor to focus efforts. PDF Epic records, fully redact names, and add subject ID to each page of every document shared. Share via a **secure file sharing system** (e.g. CHOP-managed Box, Google Drive, Citrix Sharefile). Limited redacted records may be shared via email if using [send secure]
 - For records that are only in hard copy onsite and are critical for sponsor source data verification, consider whether other staff from the department are on campus for **essential clinical research** activities. If so, consider having those individuals **complete scanning** for the team when some are still working remotely
 - CHOP-supported videoconference applications (Skype, WebEx, and Bluejeans) may be used with remote monitors to **facilitate review of limited records by screen sharing**
 - Electronic regulatory binder solutions are being evaluated; however, there are no short-term plans to implement.
 - Epic Research Champions are working on implementing a more streamlined and improved solution to access Epic
 - Contact the Office of Research Compliance with questions