Category: Training, Quality Assurance, Remote Monitoring, and Auditing – Work in Progress

Transitioning to Remote Monitoring: Challenges and Successes

H. Finch, S. Matkin, K. Thorne

Huntsman Cancer Institute, University of Utah

1. Background

As a result of the COVID-19 pandemic, clinical research oversight at Huntsman Cancer Institute immediately transitioned to a remote environment. Prior to the pandemic, our clinical site monitors had primarily reviewed paper documentation in the form of physical subject study charts. In addition, our usual practice of meeting with study teams and principal investigators (PI) transitioned from in-person meetings to virtual meetings. By shifting to a remote environment, it was necessary to adjust many of our current practices to accommodate potential delays in our oversight timelines as the pandemic unfolded.

2. Goals

According to our data and safety monitoring plan (DSMP), investigator-initiated trials (IITs) are reviewed after the first patient enrollment. Subsequent monitoring should occur every three months for high-risk trials, every six months for moderate-risk trials, and annually for low-risk trials. Our goal is to complete a single monitoring visit within one month in order to maintain compliance with our DSMP. Our goal was to maintain this timeline despite the unprecedented circumstances. Our department also provides quality assurance (QA) reviews for National Clinical Trials Network and industry studies. Our goal for QA review timelines is similar to our IIT oversight.

3. Solutions and Methods

Monitoring transitioned to direct review of our electronic medical record, Epic, instead of the paper study chart. Study teams uploaded paper source documentation electronically to a secure shared file. We worked with our clinical trials office to develop a Part 11-compliant signature system. We created an electronic case report form in OnCore, our clinical trials management system, to track queries. Our team emphasized the importance of upholding our data and safety oversight while accommodating an exceedingly fluid environment.

4. Outcomes

We saw a decrease in time spent on IIT monitoring in 2020 compared to 2019 and an overall increase in the time spent on QA reviews in 2020 compared to 2019. (See figure.)

5. Lessons Learned

During the pandemic, our department prioritized IITs to ensure compliance with our DSMP. We performed eight additional QA reviews in 2020, in comparison to 2019, with the same staffing. This demonstrates that overall productivity was not affected by remote work. Fluctuations in review timelines may have been impacted by a variety of factors, such as the following: accessibility of electronic records, increase in PI involvement during monitoring visits, virtual availability, and efficiency in working remotely as opposed to an office setting. Going forward, we plan to continue with a remote

work environment for our monitoring staff and further utilize electronic source documentation. We aim to create electronic records from the beginning instead of uploading paper documentation retrospectively, and as necessary, only complete a limited or risk-based review. If documentation needs to be uploaded, we will outline the required items at the time of monitoring notification to ensure study staff has sufficient time to provide this information.

Figure:

Year	# of IIT monitoring visits	Average # of QA reviews	Average # of days to complete IIT Monitoring	Average # of days to complete QA review
2019	49	38	37	31
2020	49	46	32	53