

Bridging the Onsite Divide in an Electronic Monitoring World

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1. Background

It was early 2020 when Moffitt Cancer Center hosted up to 32 sponsor monitors a day at an offsite Moffitt building to conduct monitoring of Moffitt participation on their studies. At this time, Moffitt's Clinical Trials Office (CTO) had completed a very successful campaign called Going Green to divest our reliance on paper documents and files. This project allowed us to facilitate "remote monitoring," since most of the onsite visits were in fact just a remote visit in disguise, by providing electronic access to Moffitt's electronic medical record (EMR), eRegulatory binder, and our electronic pharmacy records system. We did facilitate an onsite visit to the pharmacy for drug accountability and the monitor would often briefly meet with the PI to inform them how the study monitoring is going.

When the calendar flipped to March 2020, the unthinkable happened when Moffitt (like other businesses) ceased most onsite business activity outside of direct patient care activities. Over the next 2+ years, Moffitt was able to accommodate all monitoring remotely, even drug accountability, via Zoom video meetings with the Pharmacy.

In late 2022 and throughout 2023, sponsors began requesting to come back onsite for monitoring, but the space we once had was repurposed and there was literally no monitoring task that we could not accommodate remotely. After expressing the remote capabilities of Moffitt to sponsors, we were still at an impasse, as sponsors were noted that they would not bring new studies to Moffitt if we did not allow onsite monitoring. We recognized the need for a bridge to be collaborative and continue to work toward Moffitt's mission "...to contribute to the prevention and cure of cancer."

As of December 2023, Moffitt developed accommodation requests for Quarterly Onsite Facility Tours. The onsite facility tour consists of a comprehensive tour of all our spaces, facilities, and equipment that any sponsor may need to see to cover all ongoing studies and possible upcoming studies.

One to two selected representatives per sponsor are allowed to come onsite to conduct these tours once properly vetted by the Sponsor Monitoring Office.

2. Goals

- Meet the needs of sponsors (policy, contract terms) to allow onsite activity at Moffitt
- Focus the onsite time on in-person value-added items

3. Solutions and Methods:

In December 2023, Moffitt implemented a pilot to host one annual onsite tour per sponsor to meet their policy/needs for onsite access. The plan was vetted with multiple sponsor partners in advance to assure their needs would be met during the onsite time. The following outlines the process used for the pilot:

- Identified 2 sponsors for the pilot
- Requested that each sponsor identify 1-2 representatives for the onsite tour

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- Vetted the sponsor representatives through our institutional policy for onsite access
- Required each sponsor representative to wear a mask throughout the duration of the tour
- Requested that sponsor representative send any checklist or other tools they use during these visits to help us identify if we are covering their needs in advance

4. Outcomes

Once the tours were completed, feedback from the sponsor representative(s) was requested to help improve the tour process and make sure all their needs were met. The feedback attained after the pilot was that the tour met their overall needs for an onsite visit, but they did give some suggestions to help them be more prepared:

- Send the sponsor onboarding packet link in advance so they can get as much information from it as possible
- Make the calibration of equipment records available in advance

As the sponsors gave feedback, we also requested feedback from the Moffitt team to improve the process and the following were the main points we chose to implement:

- To prevent overcrowding and ensure that all areas of the tour are accessible, we will limit the number of people per tour
- We will stage tours in staggered increments to prevent taking up too much time from points of contact and minimize disruption to hospital activities
- To ensure that sponsors have seen all relevant documents, such as calibration records, we will provide them with packets containing related materials and a checklist that they must acknowledge and send back
- We will prepare a list of backup staff members for both tour guides and points of contact within the departments to ensure a smooth transition if someone is unavailable
- A follow-up meeting with the sponsor will be scheduled one week after the visit to address any questions, concerns, or missed information and avoid unnecessary follow-up visits

5. Lessons Learned and Future Directions

- Operational enhancements will be made within Moffitt Cancer Center to help execute these tours in a streamlined manner
- In order to accommodate all sponsors requesting the tour from Moffitt, in 2024, we will host tours every other month
- We will continue to collect feedback to determine if the process should be continually adapted and if we will continue the tours into 2025