



Bridging the Onsite Divide in an Electronic Monitoring World

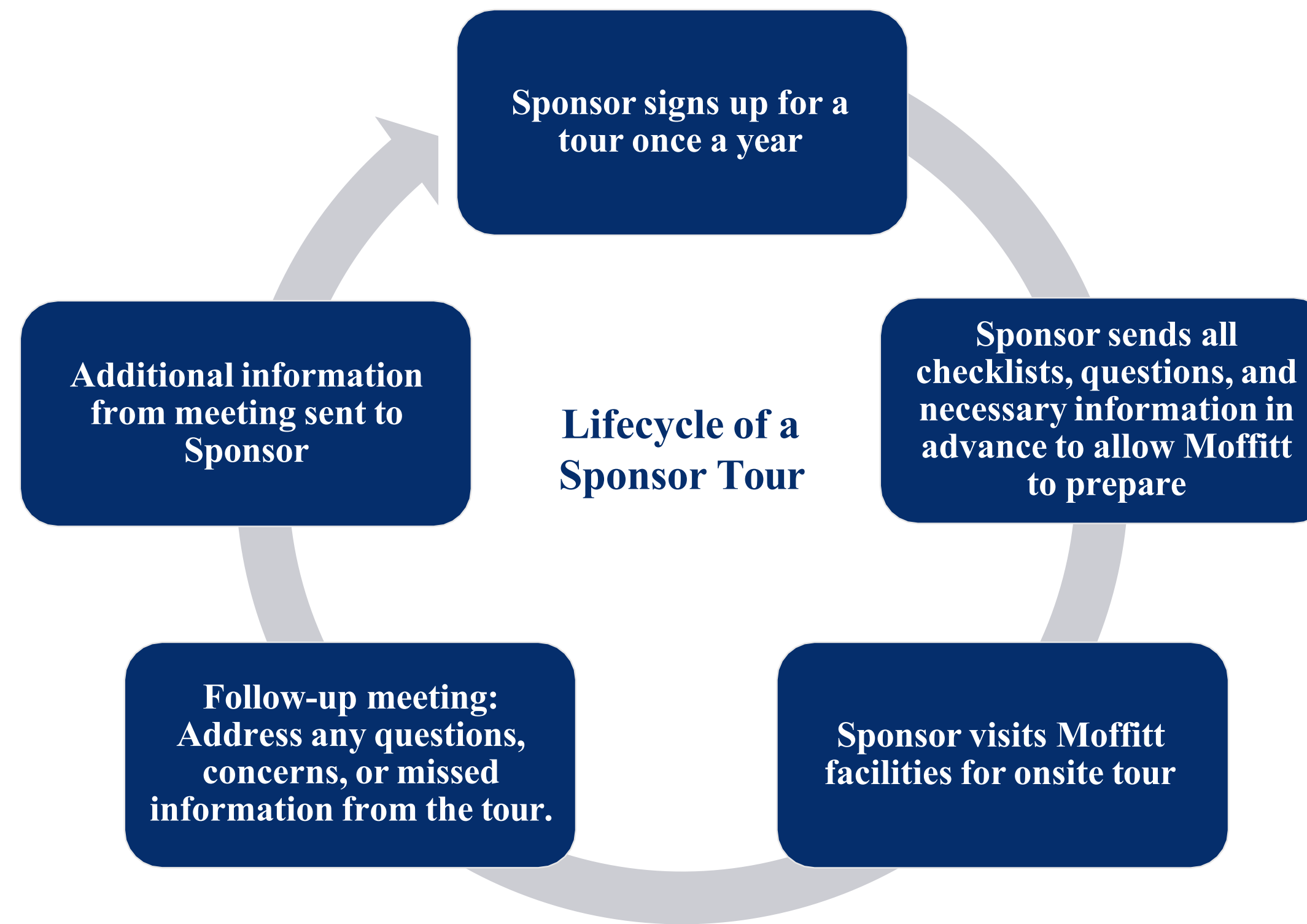
Kristie Moffett, Jamie Germain, Amber Voorhees, Deidra Ellison-Gonzalez, Marco Cid
H. Lee Moffitt Cancer Center



Background

Pre-pandemic, H. Lee Moffitt Cancer Center (Moffitt) offered some remote monitoring opportunities. As onsite operations were restricted in 2020, we were able to smoothly transition to meet sponsor monitoring needs 100% remotely thanks to our *Going Green* project. As we came out of the worst of the pandemic, sponsors began requesting onsite visits once again and we recognized the need for collaboration while still utilizing the efforts and tools implemented:

- Jan 2020: Moffitt’s Clinical Trials Office completed the *Going Green* campaign to divest our reliance on paper. The project moved us toward remote monitoring by providing access to the electronic medical records, regulatory ebinder, and electronic pharmacy system.
- Pre-pandemic, Moffitt was facilitating up to 32 sponsor monitors a day 'onsite' at an offsite administrative building.
- During the pandemic, the space designated for sponsor monitors was repurposed by the institution.
- Since March 2020, Moffitt continues to accommodate fully remote monitoring.



Lifecycle of a Sponsor Tour

Solutions and Methods

Moffitt developed an annual comprehensive tour of facilities to 1) support sponsor site validation requirements and 2) focus on tasks sponsors cannot achieve remotely. The plan was vetted with sponsor partners and incorporating their feedback, Moffitt scheduled a pilot tour in December 2023 covering Moffitt Magnolia, the new McKinley surgical hospital and one Moffitt Ambulatory Clinic (MAC), which serves as the example of all other MACs.

The following outlines the process used for the pilot:

- Identified 2 sponsors for the pilot
- Requested each sponsor identify 1-2 representatives for the onsite tour
- Vetted sponsor representatives through our institutional policy for onsite access
- Each sponsor representative must wear a mask throughout the tour
- Requested sponsor representative send any checklist or other tools they use during these visits to help identify if needs are covered in advance.

Pilot Lessons Learned

- Logistical changes were needed to streamline tour efficiency
- Need to host tours every other month in 2024 to accommodate all sponsors
- Collecting feedback from sponsors to continuously improve the tours to meet sponsor needs
- Assure sponsor reviewed Moffitt’s *Sponsor Welcome Packet* and equipment calibration records sent in advance since they answer many of the sponsor’s questions in advance

Outcomes

Once the tours were complete, feedback from the sponsor representative(s) and Moffitt team members was requested to help improve the tour process and make sure all needs were met.

Sponsor feedback:

- The tour met their overall needs for an onsite visit.
- Provide the sponsor onboarding packet in advance since it answered many sponsor questions.
- Provide the equipment calibration records in advance.

Moffitt team member feedback:

- To prevent overcrowding and ensure that all areas of the tour are accessible, we limited the number of people per tour.
- Stage tours flow to minimize time spent by Moffitt point of contacts and minimizing disruption to operations.
- Backup staff members necessary for tour guides and department point of contacts to ensure continuity.
- Follow-up meeting with the sponsor one week after the visit (if needed) to tie up loose ends.



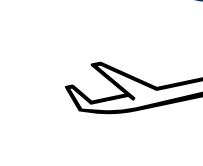
Jan. 2020
Moffitt “Going Green”
Project Completed



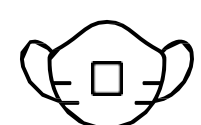
2020
Moffitt accommodated all
monitoring remotely



Dec. 2023
Pilot Onsite Tour: Positive
feedback and results



Apr. 2024
First official facility tour



Mar. 2020
Pandemic: Moffitt limited
onsite business activity
outside direct patient care



2022–2023
Received requests from sponsors
to come onsite so began planning



2024
Established final onsite
facility tours



May 2024
Six additional sponsors
scheduled for tours
throughout 2024