

Sponsor Monitoring Office: A New Way to Facilitate Remote Interim Monitoring

Jamie Germain, Kristie Moffett, Cheryl Maker, George Barker, Mackenzie Mitchell

Background:

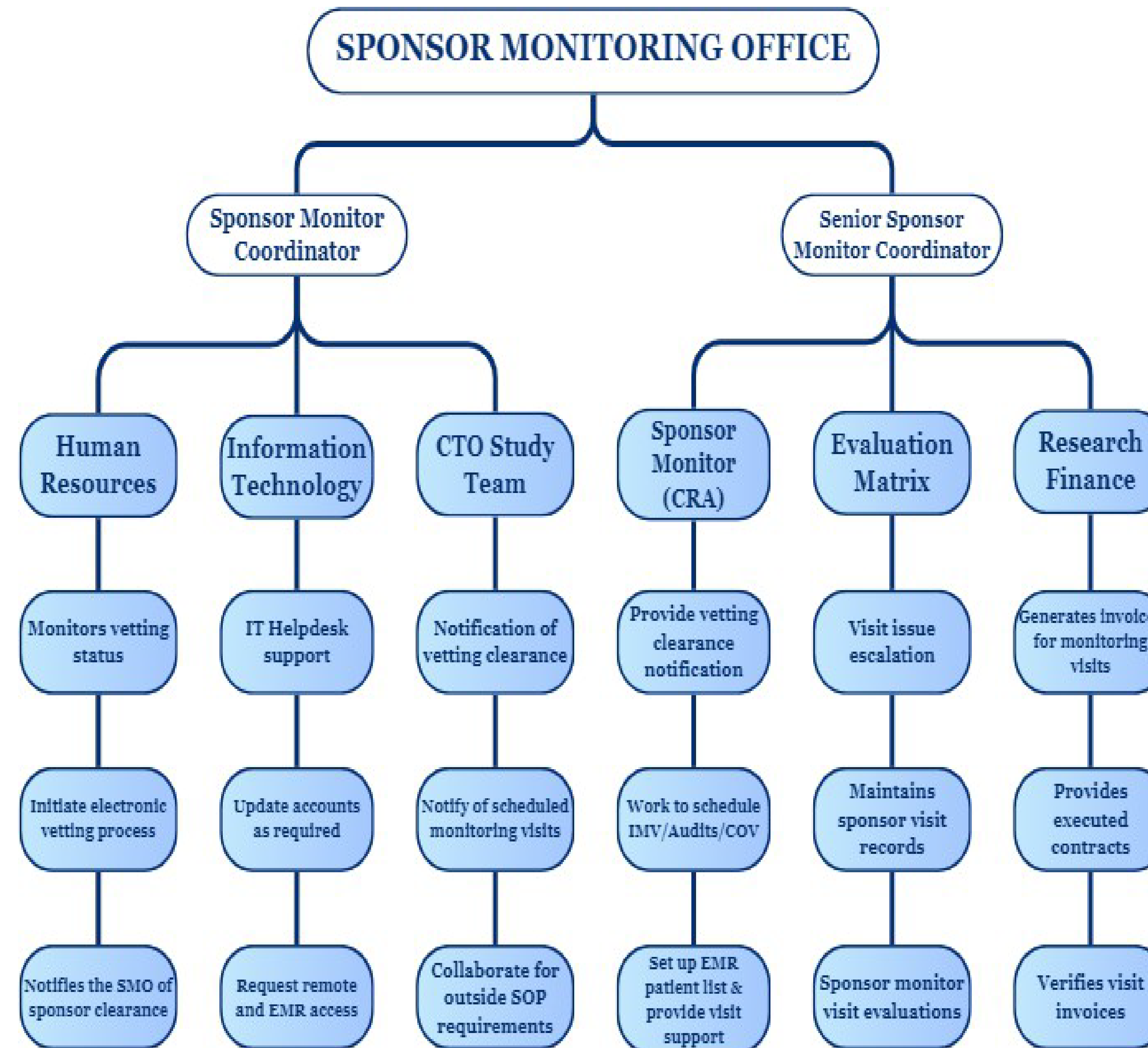
Establishing the Sponsor Monitoring Office In 2015, an evaluation was completed on the process for vetting sponsor monitor access requests for H. Lee Moffitt Cancer Center's (Moffitt) electronic medical record (EMR). This was due to the complexity of the process and the time it took to obtain approval and troubleshoot access issues.

After review of the effort from all staff involved in the process, a decision was made to centralize the workflow, which established the Sponsor Monitoring Office (SMO). The SMO began with one full time employee (FTE), who worked as the liaison for the process. This role became the main point of contact to set up accounts with Information Technology (IT), schedule the monitoring visits, load patient lists in the EMR, and to facilitate troubleshooting access issues. It also became the liaison to the following groups: internal study teams, Human Resources (HR), Research Finance, IT, and external sponsor monitors and auditors.

Goals:

Remove the facilitation of the sponsor monitor vetting process and administrative tasks from the study teams:

- Scheduling sponsor monitor visits
- Loading patient lists in the EMR
- Support and troubleshoot sponsor monitor access
- Manage sponsor monitoring access: Terminations, account changes, and collaboration with Compliance on audits.
- Recording the revenue of the confirmed monitoring visits, data locks, monitoring change fees and audits.
- Maintaining the SOPs/Policies

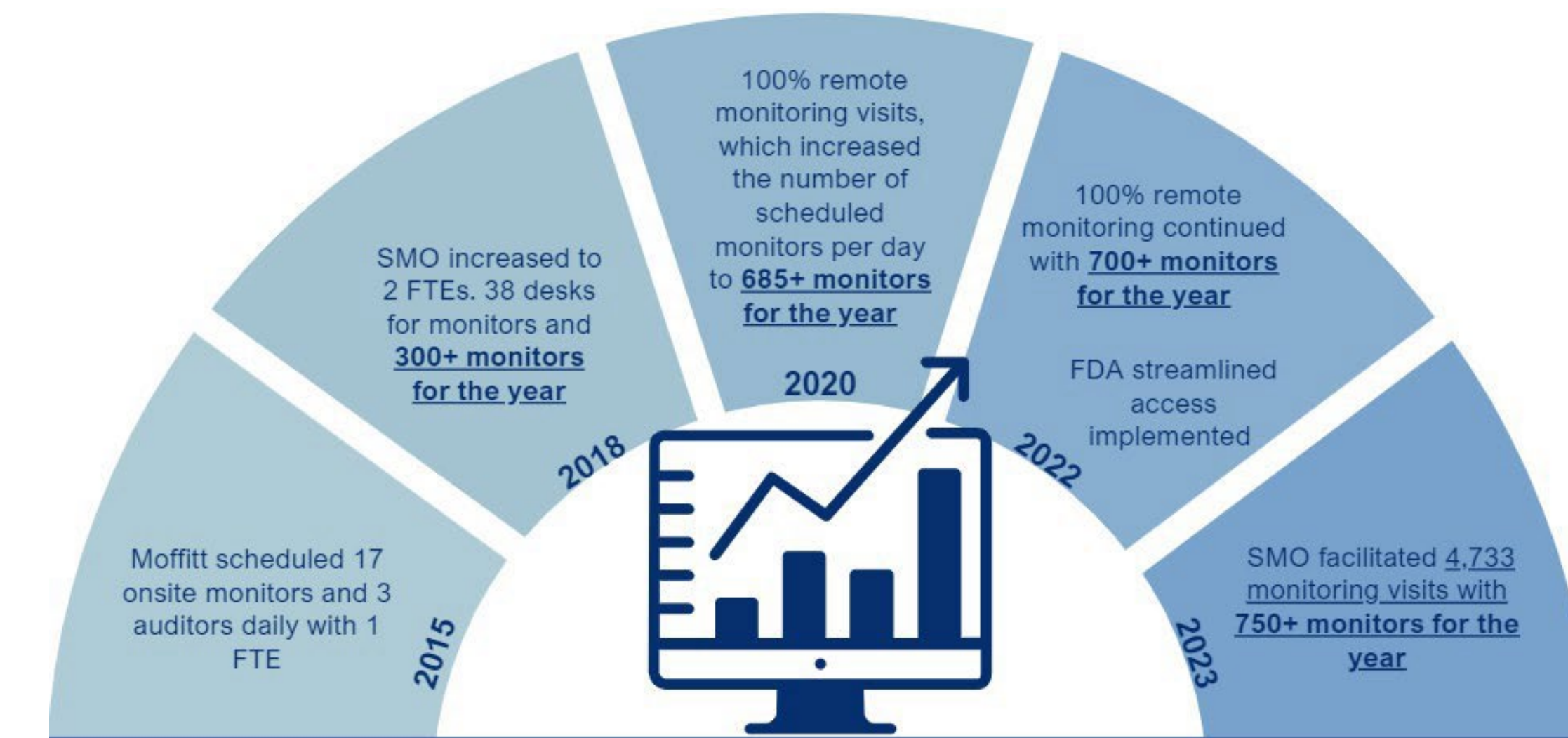


The visual above is used for organizational planning to identify the roles and responsibilities of the SMO and other collaborators. There are currently two levels of Sponsor Monitor Coordinators, and they are cross-trained to provide consistent support to the sponsor monitors and coverage for the team.



Growth and Outcomes:

- Immediate access for FDA Inspectors
- 2 FTEs support 30 sponsor monitors per day
- Hours of operation: Monday-Friday 7:45am-4:45pm
- Accommodate different time zones (as needed)
- Open 50 weeks per calendar year: Closed for 2 weeks during holidays



Growth from 2015 to 2023

Insights Gained and Future Direction:

Initially, it took the sponsors time to get used to reaching out to SMO to schedule monitoring visits.

- The key to making the change was consistency and adhering to the new process. We did not allow anyone to go around it.
- Developed a monitoring policy to outline the expectations and process:
 - Two sponsor monitors allowed per scheduled visit
 - Number of monitoring days per month limited
 - Additional monitors/days can be requested for certain circumstances.
- Increasing need for more monitoring visits so considering adding an additional FTE to support more visits per day.
- The team continues to streamline operations, quality and compliance of each monitor, and our processes as they evolve over time to help assist the Study Teams

Contact: Jamie Germain, MSM, CRA, HSR Director
Email: jamie.germain@moffitt.org