Monday Morning Practice Pearls #73

What needs to be done for a monitoring/audit visit and who is responsible?

It depends on the protocol and the sponsor.

- Office of Sponsor and Regulatory Oversight (OSRO) oversees **all** CCR-sponsored protocols and the Sponsor Regulatory Oversight and Support (SROS) is the group that monitors CCR-sponsored studies.
- Industry-sponsored studies may use in-house monitors or work with a Contract Research Organization (CRO)to provide monitoring, depending on the sponsor/pharmaceutical company.
- Audits for CTEP-sponsored studies (including NCI Network audit: ET-CTN, NRG Oncology, Alliance, etc.) typically will have multiple protocols across different teams being reviewed at a visit.
- All other non-IND/IDE protocols conducted in the CCR do not have sponsors but may have audits done by OEC or designee (e.g., ASRC) as part of the CCR Quality Management Program.

Sponsor	Monitoring / Audit Group	Regulatory Files	Access to Medical Records	"Paper" Research Records
OSRO	SROS	Uploaded to Veeva Vault by PSO Manager; Monitor has access to Veeva Vault by OSRO directly; Box is not used	Study coordinator must request access to the Clinician Portal for the monitor via the Regulatory Audit Scheduling Portal and a list of patients to be reviewed must be sent to "CC-HIMD Regulatory Audit" no later than the Wednesday prior to the scheduled visit	Study coordinator sends via Secure Email File Transfer (SEFT) to monitor
Industry	Sponsor or CRO	OEC/PSO Manager work together to upload files into Box; OEC will give Box access to monitor so need to be aware of visit		Study coordinator sends to OEC for upload into Box
CTEP / NCI Network	Theradex / Network auditors	OEC/PSO Manager work together to upload files into Box; OEC will give Box access to monitor so need to be aware of visit	OEC will schedule the visit with HIMD via the portal and provide the patient list	Study coordinator sends to OEC for upload into Box
N/A	ASRC	Have read-only access to regulatory files on Network	Have read-only access to CRIS, no HIMD scheduling is required	Study coordinator sends via encrypted email to monitor

Please make sure that OEC is notified about **all** industry sponsored monitoring/audit visits. SROS and ASRC will typically include the QA mailbox (which includes OEC) when sending confirmation emails about visits.

For more details, please review the following CCR SOPs found on the CCR SOP website

- PM-13: Industry-Sponsored Studies Monitoring and Audit Visits
- PM-13a: Center for Cancer Research Sponsored Studies Monitoring and Audit Visits
- PM13b: Monitoring and Audit Visits by ASRC (Arctic Slope Regional Corporation)