Peer-to-Peer Data Monitoring Review

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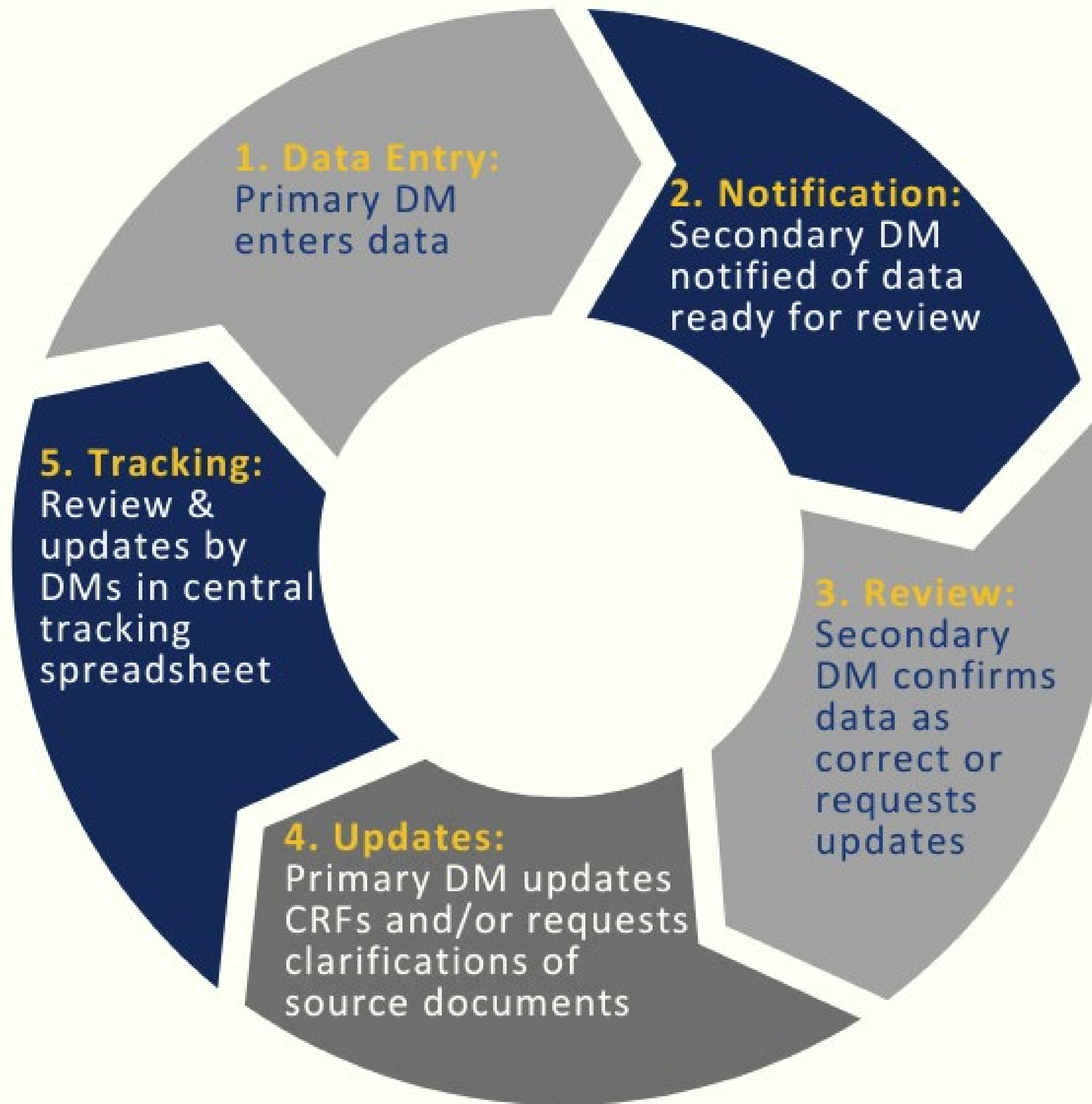
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Background

In 2023, approximately 45% of participant enrollment at the West Virginia University Cancer Institute Clinical Research Unit (WVUCI CRU) was to cooperative group trials. Many of these trials do not include routine sponsor monitoring. Historically, staff at the WVUCI CRU have conducted reviews in preparation for external audits, every 3 years, resulting in small or repeat errors being discovered possibly years later, after multiple cycles.

Goals

- Initiate data manager (DM) peer-to-peer monitoring at our main site.
- Increase compliance, timeliness, & accuracy of data submission & query resolution.
- Identify & correct errors contemporaneously.
- Identify issues before they become repeat errors.

Methods

- Developed and implemented a peer-to-peer data monitoring plan, with input from CRU DMs.
- Standardized review checklist for reviewers use.
- Secondary reviewers identified for each trial/participant enrolled since previous NCI audit (Aug 2022).
- Clear expectations set for primary and secondary DMS.
- Biweekly meetings with DM and QC supervisors to discuss progress, challenges, & to assign new patients.
- Individual meetings held when required.

Cyclical diagram:
1. **Data Entry:** Primary DM enters data
2. **Notification:** Secondary DM notified of data ready for review
3. **Review:** Secondary DM confirms data as correct or requests updates
4. **Updates:** Primary DM updates CRFs and/or requests clarifications of source documents
5. **Tracking:** Review & updates by DMs in central tracking spreadsheet

Outcomes

- Historic patient reviews completed Jan 2024. Future monitoring to be completed within 6 weeks of data entry.
- Repeat data errors identified, corrections & reeducation completed:
  - Increased usage of central source data verification & uploaded documents, therefore increased risk in inadvertently uploading PHI. Bi-weekly DM meeting provides opportunity to review repeat errors & complete necessary retraining.
  - Increase in solicited adverse events in Rave, but not identified in the protocol. DMs reminded to flag to research coordinators when documentation is not available in source.
- Improvement on SWOG expectation report from Sep 2023 through to Dec 2023, from 18 late forms to 5 late forms.
- DMs reported more confidence problem solving issues with sample submission; currently no samples pending.

Lessons Learned

- Initial phase of reviews was more time consuming than anticipated due to:
  - Uneven distribution trials resulting in uneven workload for providing responses and updates.
  - Back log in data entry due to a long-standing DM, following ~175 patients, retiring earlier than expected, and a new hire requiring training.
  - Locked eCRFs.
- Varied account set-up within EMR, e.g., confirmation of auto-injector rates and b values on an MRI trial.

Future Directions

- Implement at affiliate sites
- Implement for IITs
- Demonstration of staff growth and improvement