Learning Evaluation and Advancement Plan (LEAP)

F. Kerr, S. Asche, C. Bucks, K. Carew, S. Roby, B. Kloczkowski, H. Willis

Indiana University Melvin and Bren Simon Comprehensive Cancer Center

1. Background
The Indiana University Melvin and Bren Simon Comprehensive Cancer Center (IUSCCC) began performing data checks on staff in 2011. In these early days, data checks were reserved for Investigator Initiated Trials (IITs) and served a dual purpose of satisfying the data and safety monitoring committee (DSMC) review for these trials. As staffing and workload complexity increased, the data check process evolved into a Probationary Data Check (PDC), during which all new staff were reviewed at their 6-month mark and expanded to capture all trial types. PDCs evaluate protocol, regulatory, and policy compliance, regardless of the staff member's role on the study. Overall grading of pass/fail was a subjective judgement call from the Quality Team. While all staff were subject to a PDC and Team Managers are involved in all close-out meetings, this information was rarely used for performance improvement. Additionally, overall numbers of types or categories of findings were not tracked. Follow up with teams to ensure all items are resolved and responded to was time consuming and there were no repercussions for staff failing to resolve issues.

2. Goals
1. Provide an evaluation system with clear pass/fail criteria.
2. Move from a paper-based to electronic system.
3. Create reporting within electronic system to track trends.
4. Clearly outline the process and repercussions for failing to respond/complete data check.
5. Use PDC as a tool to evaluate staff for potential role advancement.

3. Solutions and Methods
- Work with IT to create an electronic portal.
- Adopt the National Clinical Trials Network (NCTN) Clinical Trials Monitoring Branch (CTMB) Auditing Guidelines for pass/fail criteria.
- Work with IT to build reporting within electronic system to track trends.
- Work with clinical trials office (CTO) administration to identify repercussions and performance improvement based on data check outcomes and failure to complete/respond to data check report.
- Create CTO standard operating procedure (SOP) to outline the data check process expectations, repercussions, and advancement evaluation.
- Rebrand PDC to Learning Evaluation and Advancement Process (LEAP) to reflect updates.

4. Outcomes
The Quality Team and IT have created an online portal to enter and track LEAP findings, utilizing the NCTN CTMB Auditing Guidelines for overall outcome scoring. The portal is still being tested for new reviews with feedback provided to the IT for updates. Overall outcome is clearly labeled for each LEAP review with both words (Acceptable, Acceptable Needs Follow-Up, Unacceptable) and color (green, yellow, red). IT is still currently in the process of building trend reports. Final outcome reports are

available for staff being evaluated with checkoff boxes to indicate when a finding has been resolved or comment boxes for more information. The portal has been designed to send automatic email reminders at one week and two weeks after the close-out meeting. Staff who fail to complete LEAP resolution will be referred to the Team Manager for potential disciplinary action.

5. Lessons Learned and Future Directions

As the Quality Team has been testing the system there have been several rounds of updates and improvements that are still ongoing. Current struggles are ensuring staff-facing final reports include all relevant information, different evaluation criteria within the portal may need different input methods that are still being identified and built. CTO SOP creation and guidelines for advancement review and performance improvement/repercussions are ongoing.