

Learning Evaluation & Advancement Plan (LEAP)

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1. Background

The IUSCCC began performing data checks on staff in 2011, focusing on Investigator Initiated Trials (IITs) and serving a dual purpose of satisfying the Data 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) with all new staff reviewed at their six-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 from the Quality Team. While all staff were subject to a PDC and Team Managers were involved in all close-out meetings, the results were infrequently leveraged as opportunities for professional development or process improvement. Over the past year the Quality Team and IT have created and piloted an online portal to enter and track Learning Evaluation and Advancement Plan (LEAP) findings with increased enhancements to ensure proper data is being captured and reported.

2. Goals

1. Outline the process and developmental opportunities for failing to resolve data checks and Unacceptable data check results
2. Use PDC as a tool to evaluate staff for potential role advancement
3. Use data as a part of our "Health of the CTO" dashboard for leadership
4. Build clear and concise metrics reports that display findings based on specific report criteria

3. Solutions and Methods

- Continuous testing of current electronic portal to pinpoint enhancements needed for proper reporting and education purposes
- Determine depth of reporting metrics and work with IT to build this out in the electronic system.
- Add visualizations of findings to capture data points across different variables
- Create a detailed SOP and guidance of LEAP to ensure consistency in reviewer evaluations, thus leading to more accurate metrics reporting, developmental opportunities, and greater staff understanding
- Rebrand PDC to 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 continually tested for areas of improvement and addition of new details that will aid in better reporting. Overall outcome is clearly

labeled for each LEAP review with both words (Acceptable, Acceptable Needs Follow-Up, Unacceptable) and color (green, yellow, red). Recent updates include a progress bar to see the status of staff review and completion of corrections. Outcome reports are available for staff being evaluated; checkoff boxes indicate resolved findings, and comment boxes to provide more information. Enhancement requests include building trend reports, sending automated email reminders post close-out meeting, and corrected scoring. Staff who fail to complete LEAP resolution will be referred to the team manager for potential disciplinary action or additional training.

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. While we implemented a new scoring system, it was noted that it did not properly reflect the number of findings appropriately. A new scoring system is currently being developed. We are working to add new tabs to the data check portal to house our tracking spreadsheet, as well as other reviews that we complete within the CTO (eReg review and NCTN chart reviews). Once the new metric reporting feature has been rolled out, we will be able to begin pulling reports and analyzing trends that are occurring within our office and within the different roles. This will allow us to pinpoint areas of improved training and implement process improvements office wide.