# Learning Evaluation & Advancement Plan

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Background

The 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 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. Over the past year the Quality Team and IT have created and piloted an online portal to enter and track LEAP findings.

Goals

1. Fine tune the electronic system to ensure it covers the necessary reporting metrics.

2. Determine how the reporting metrics can identify trends across staff performance and study type.

3. Breakdown and detail finding types to correlate with major/minor categories.

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.

6. Use data as a part of our "Health of the CTO" dashboard for leadership.
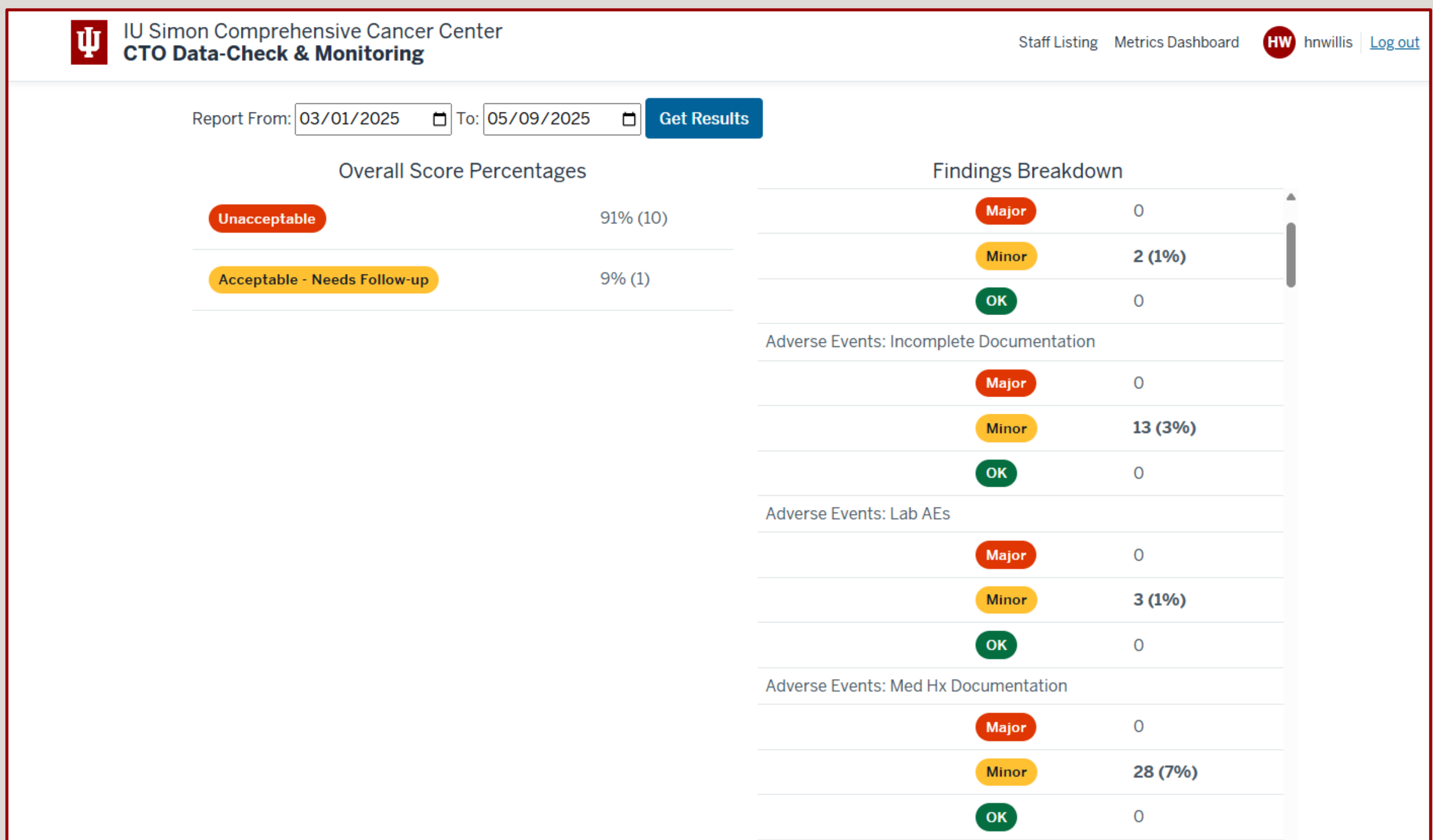
Materials & Methods

- Test current electronic portal to pinpoint adjustments or additions needed for proper reporting and education purposes.

- Determine depth of reporting metrics and work with IT to build this out in the electronic system.

- Create detailed list of finding categories and examples to ensure consistency in reviewer evaluations thus leading to more accurate metrics reporting and greater staff understanding.

- Create CTO SOP to outline the data check process expectations, repercussions, and advancement evaluation.

- Rebrand PDC to Learning Evaluation and Advancement Process (LEAP) to reflect updates.

Results

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 being tested on all new reviews with feedback provided to IT for updates. The creation and use of this portal has allowed a centralized location for PDC findings. By using this new system, the Quality Team has been able to transition from the paper form and streamline the process from "monitor" to staff side. Staff receive a unique link that takes them to their finding page where they are can see the finding, category and action requested along with an area for comment. This allows them to directly respond to findings in the portal rather than having to send a paper document back and forth.

Conclusions

As the Quality Team has been testing the system there have been several rounds of updates and improvements that are still ongoing. Currently the report shows the overall percentages of acceptable- needs follow up, unacceptable and acceptable findings, along with the breakdown of the specific findings categories. The next steps are to build out the metrics reporting system to encompass findings at a broader CTO level down to a staff specific level. Current struggles are ensuring the system is intuitive to use, captures the necessary information for the evaluation reports, and IT failures within the system leading to loss of data or the need to reprogram, test, and re-enter data. CTO SOP and guidance creation for performance improvement/repercussions are in progress.