Category: Regulatory – Work in Progress

Developing a Tool to Assess Regulatory Acuity and Workload

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1. Background

Accurately assessing the personnel resources needed to support the regulatory component of clinical trial operations is crucial to the effective conduct and management of clinical research portfolios. The absence of a validated assessment tool for regulatory resourcing assessment, such as OPAL for clinical resourcing, makes the assessment of necessary regulatory personnel resources and appropriate staffing more challenging within a clinical trial organization (CTO). Without a formal mechanism to assess current regulatory staffing resource needs and anticipate future regulatory staffing resource needs, CTOs are left to react to staffing shortages instead of proactively planning for and anticipating the needs of the team. This leaves staff feeling overworked and may impact morale and staff turnover adversely.

2. Goals

The goal of this project is to develop and pilot a new regulatory acuity and workload tool that will assess workload and capacity of regulatory staff through the utilization of metrics. The reporting of these metrics will inform regulatory and CTO leadership of the needed staffing resources to support existing disease team workloads and allow for projection of resource changes over time as the cancer center trial portfolio expands and contracts.

3. Solutions and Methods

Our regulatory acuity and workload tool assigns an overall score to the trial portfolio for each disease group. The score is calculated based on the following variables for each study in the portfolio: study status (new, protocol review committee-approved, open to accrual, closed to accrual with patients in follow-up, closed to accrual without patients in follow-up, suspended), sponsor type (institutional [UNC or non-UNC], national, industry-sponsored), phase of study (Phase I, I/II, II, III, pilot), type of institutional review board (IRB) of record (local, commercial, NCI Central IRB), and investigational new drug (IND) score (UNC held, single patient IND, non-UNC held). Each criterion is scored from 1 to 3, with 1 indicating an assessment of fewer resources needed to manage the regulatory workload and 3 indicating an assessment of greater resources needed. The total score for each study and for the disease group in total is tabulated and compared against the institutional standard set for each regulatory role — regulatory associate and regulatory assistant. Utilizing this tool, we are then able to determine if the personnel resources for the disease team portfolio are sufficient based on the overall portfolio score and a comparison of historical metrics. These metrics have been shared with disease team leaders at bi-annual disease team meetings since 2018.

4. Outcomes

Our regulatory acuity and workload tool has allowed us to more accurately track current staffing needs based on the current study portfolios for our disease teams and anticipate needed staffing adjustments based on anticipated portfolio growth. In addition, as new disease teams and stakeholders have joined our CTO, our regulatory acuity tool has allowed us to more accurately evaluate the personnel needed to

support the additional work of our growing CTO trial portfolio. The presentation of this data to disease group leaders has been very well received, providing transparency in resource allocation decision making. It has also allowed CTO leadership to incorporate anticipated growth in the regulatory workforce into annual budgeting exercises.

5. Lessons Learned

From the development of this tool, we learned that historically our office had been understaffed with regards to regulatory support for our disease teams' portfolios. With the development of this tool, we have been able to more accurately assess the personnel resources needed to support the regulatory workload for our disease teams' growing trial portfolios. In order to enhance our tool's ability to more fully assess the resources needed for regulatory support, we are working to explore ways to leverage additional trial data currently stored in our clinical trial management system, OnCore.

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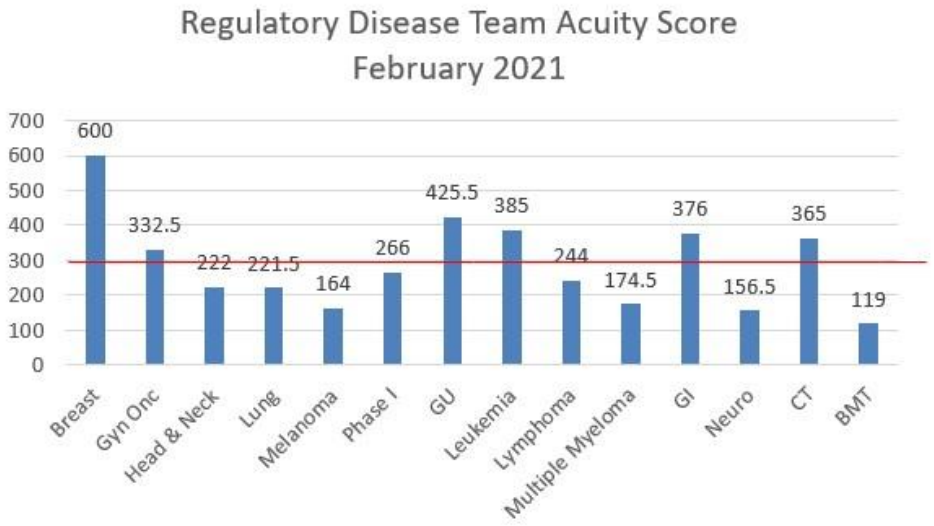
The chart below shows the regulatory acuity score for each disease group in the CTO compared against the institutional standard of 300.



The chart below shows the number of full time equivalents (FTEs) needed for each disease group as calculated by dividing the acuity score for each disease group by the instituitonal standard of 300.