*Category: Clinical Trial Operations (Trial Start-up, Regulatory, Data Management, IITs) – Completed Project*

**Utilizing OnCore Annotation Tab to Track Regulatory Team Acuity: A Workload Assessment Tool**

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**1. Background**

The Clinical Trials Office (CTO) of IU Simon Comprehensive Cancer Center has implemented several workflow process changes as well as introduced new research systems within the last two years. As a result, we have seen a significant increase in the responsibilities of the regulatory compliance coordinator (RCC) role. With added responsibility of the RCC role and the increase of clinical trials complexity, it is prudent to accurately assess workload across the regulatory team. A workload assessment tool not only ensures that the workload is evenly distributed but also provides justification for future positions. An evenly distributed workload amongst a team has been proven to add to job satisfaction and retention. The CTO regulatory manager realized that a regulatory acuity scoring tool already existed in OnCore but was not currently in use. They reached out to the research systems analyst and cancer center data analyst to inquire if the tool could be resurrected and redesigned to meet our current needs.

**2. Goals**

- Update an antiquated regulatory acuity scoring tool in the OnCore annotation tab to reflect current responsibilities of the RCC role.
- Create a report and review results of regulatory acuity scores to assess workload and redistribute as needed.
- Use data and metrics from report for future justifications of additional full-time equivalents (FTEs).

**3. Solutions and Methods**

Through collaboration with the research systems analyst and data analyst, the CTO regulatory manager was able to update the antiquated regulatory acuity tool that previously existed in OnCore. A list of questions was created that accurately reflected regulatory responsibilities from study start-up through study closure. Each responsibility was assigned a value depending on the complexity of the work. The result was a calculated acuity score for each study protocol. An OnCore report was then created that pulls the total calculated acuity score for all studies that the RCC is assigned on the OnCore staff tab.

**4. Outcomes**

We found that the accuracy of the OnCore regulatory acuity report is dependent on the RCC being listed on each assigned protocol on the OnCore staff tab, as well as manual completion of the form on the OnCore annotation tab. The team ensured that all CTO managed studies were updated to accurately reflect assigned RCC and that the regulatory acuity form was completed for each trial. As expected, the report showed higher acuity scores for complex studies and was able to indicate that several RCCs had a much higher acuity score than their colleagues.

**5. Lessons Learned and Future Directions**

- Learned that larger volume of studies does not always equal a larger workload. Due to the complexity of trials, a regulatory compliance coordinator may have a lower number of trials but equal regulatory workload acuity.

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- Moving forward, the regulatory acuity report will be reviewed quarterly to assess regulatory compliance coordinators' workload. This will allow for an even redistribution of responsibilities as needed.
- The data provided from the regulatory acuity report will provide metrics needed in justification for additional FTEs as needed.

**Figures**

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| CTO | Number of Trials: | 393 | RCC | Number of | 66 |
| | Total Acuity Score: | 1979 | | Total Acuity | 335 |