Not All Studies are Created Equal: A Method to Track Regulatory Service Staffing

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Background

As research is constantly changing, a need was identified to track protocol complexity as it relates to regulatory needs. Traditional workload models that assign a fixed number of studies per regulatory coordinator fail to account for substantial variation in study design, regulatory burden, and operational complexity.

Goals

- To implement a systematic approach for tracking regulatory services (IRB submission, research committee submissions, electronic regulatory document management).
- Develop an acuity tool that incorporates key study variables to assess workload and inform staffing needs.

Solutions and Methods

A regulatory acuity tool was developed in OnCore to quantify study complexity by evaluating variables that influence regulatory workload. Existing OnCore variables were used, and weighting was assigned to each variable based on assumptions reviewed and validated by multiple stakeholder groups. Examples include: Phase I trials typically undergo more frequent amendments than Phase III trials, and interventional trials require more regulatory support than observational studies. Additional variables incorporated into the scoring model include study phase, sponsor type, protocol type, number of participating locations, required research committee reviews, number of informed consent documents, and study status.

Outcomes

The acuity tool enables dynamic assessment of regulatory workload across teams, disease groups, and individual coordinators.

Automated reporting provides a total acuity score per protocol, which can be aggregated to evaluate FTE needs and track workload fluctuations as portfolios evolve.

In addition, the tool supports performance management and coaching efforts. For example, if a staff member's acuity level is below their established baseline, yet they are still experiencing difficulties, this may indicate a need for targeted coaching, workflow review, or performance improvement.

Lessons Learned and Future Directions

Organizational structure and regulatory processes vary across Cancer Centers; therefore, variable selection and weighting may require site-specific customization.

Future work will focus on refining the model and conducting staffing projections as new protocols come through.

Opportunities for broader implementation of the tool could include burnout prevention, and the ability to assign studies based on complexity.

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