Development and Implementation of a Research Study Regulatory Complexity Assessment Tool

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Abstract

Oncology clinical trials are among the most active and longest in duration in the area of drug trials. Research suggests, trials are becoming more complex with varying designs, objectives, and endpoints. Regulatory affairs is crucial to the success of these trials to ensure adequate regulatory document maintenance throughout the conduct of the trial. However, limited information is available on the impact of increased trial design on the regulatory complexity of a clinical trial. Regulatory complexity assessment tools can be utilized to collect and evaluate relevant clinical trial factors to effectively manage workload distribution, perform quality assurance review, and calculate future portfolio projections. Understanding the scope of regulatory complexity is essential to ensuring there is appropriate regulatory support and infrastructure to demonstrate the trial’s compliance.

Methods

• Developed stakeholder consensus as to factors which contribute to regulatory complexity.

• Partnered with the vendor, Office of Clinical Research (OCR), and Information System (IS) collaborators to leverage information on the study details in the cloud-based application to create Research Team specific study level reports based on trial phase, study status, and organizations such as IRB of record, regulatory sponsor, CRO, number of products.

• Developed and implemented generalizable weighting scale from least to most regulatory effort based on factors list above.

• Analyzed and reviewed research team portfolios undertaken within the Unit.

Results

Leveraging the regulatory complexity assessment report as part of the toolkit in portfolio oversight assisted in addressing concerns about equitable distribution of resources within the ACC-CRU-ORA supporting the Unit. It has increased transparency between ACC-CRU-ORA staff and managers in meeting compliance expectations as there can now be a real time report of regulatory complexity for the portfolio which a staff member manages. Not only is this useful for current staff, but also when onboarding and training new staff to determine which types of trials are most appropriate for training purposes and to match regulatory skill sets with portfolio. Users can now review an entire portfolio of work on an equal rating scale. As new studies are approved or old studies are terminated, a user can see in real time portfolio complexity.

In the future, we aim to use the compilation of assessments to track trends and create more precise projections to ensure the ACC-CRU-ORA is appropriately resourced to manage the Unit’s research portfolio and keep pace with the rapidly developing oncology clinical trial landscape.

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