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.

Introduction

In the Abramson Cancer Center Clinical Research Unit, Office of Regulatory Affairs (ACC-CRU-ORA) is capable of running a report in a cloud based application on the composition of the Center's research portfolio as a result of adopting an e-regulatory system. Study demographics are a required data point for the study creation in the system.
Our goal was to leverage a cloud-based eRegulatory investigator site file system to create a regulatory complexity assessment tool thereby increasing understanding of each Research Teams' and the Unit's portfolio so that appropriate resources are allocated to maintain regulatory compliance, protect human capital, and best match staff expertise with portfolio complexity.

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.

Research Team A: Portfolio Complexity Report

Study Identifier	Phase	Sponsor	Status	IRB of Record	CRO	Number of Products	Regulatory Review Level	Total Compexity Score
Trial OO	N/A	Federal	Active	Academic-Central	Emmes	0	Expedited	20
Trial II	N/A	Federal	Active	Academic-Central	None	0	Expedited	20
Trial KK	N/A	Federal	Active	Academic-Central	None	0	Expedited	20
Trial NN	N/A	Federal	Active	Academic-Central	None	0	Expedited	20
Trial JJ	N/A	Federal	Active	Academic-Local	None	1	Expedited	24
Trial O	N/A	Federal	Active	Academic-Local	None	1	Convened	26
Trial FF	Phase III	Federal	Active	Federal-Central	None	1	Convened	27
Trial GG	Phase III	Federal	Active	Federal-Central	None	2	Convened	27
Trial R	N/A	Industry	Active	Commercial-Central	None	3	Convened	28
Trial U	N/A	Industry	Active	Commercial-Central	None	3	Convened	28
Trial LL	N/A	University	Active	Academic-Local	None	0	Expedited	28
Trial MM	N/A	University	Active	Academic-Local	None	0	Expedited	28
Trial PP	N/A	University	Active	Academic-Local	None	0	Expedited	28
Trial M	Phase II	Federal	Active	Academic-Central	Emmes	4	Convened	29
Trial V	Phase II	Federal	Active	Academic-Central	Emmes	5	Convened	29
Trial Y	N/A	Industry	Active	Commercial-Local	None	1	Convened	30
Trial L	Pilot/Feas	University	Active	Academic-Local	None	1	Convened	30
Trial AA	N/A	University	Active	Academic-Local	None	1	Convened	30
Trial S	Phase II	Federal	Active	Academic-Central	None	7	Convened	31
Trial BB	Phase I/II	Federal	Active	Academic-Central	None	8	Convened	31
Trial RR	N/A	University	Active	Academic-Local	None	4	Convened	32
Trial QQ	N/A	Industry	Active	Academic-Local	None	1	Expedited	32
Trial F	Phase III	Federal	Active	Academic-Central	Emmes	4	Convened	33
Trial C	Phase II	Industry	Active	Commercial-Central	None	2	Convened	33
Trial J	Phase II	Industry	Active	Commercial-Central	None	1	Convened	33
Trial HH	Phase II	Federal	Active	Academic-Local	Medpace	0	Expedited	35
Trial T	Phase II/II	Industry	Active	Commercial-Central	None	1	Convened	35
Trial W	N/A	Industry	Active	Academic-Local	None	6	Convened	36
Trial K	Phase I/II	Industry	Active	Commercial-Central	Covance	2	Convened	39
Trial G	Phase III	Industry	Active	Academic-Central	Emmes	2	Convened	39
Trial EE	Phase III	Federal	Active	Academic-Local	None	7	Convened	39
Trial D	Phase I	Industry	Active	Commercial-Central	None	8	Convened	41
Trial DD	Phase I	Industry	Active	Academic-Central	PPD	1	Convened	41
Trial H	Phase III	Industry	Active	Academic-Local	Emmes	2	Convened	43
Trial E	Phase III	Industry	Active	Commercial-Central	Medpace	3	Convened	43
Trial X	Phase III	Industry	Active	Commercial-Central	Medpace	2	Convened	43
Trial P	Phase I	Industry	Active	Academic-Local	None	2	Convened	43
Trial Q	Phase I	Industry	Active	Academic-Local	None	3	Convened	43
Trial CC	Phase I	Industry	Active	Academic-Local	None	2	Convened	43
Trial N	Phase I	Industry	Active	Academic-Local	Parexel	3	Convened	45
Trial B	Phase III	Industry	Active	Academic-Local	Syneos Health	4	Convened	47
Trial A	Phase I	Industry	Active	Academic-Local	ICON	3	Convened	49
Trial Z	Phase I	Industry	Active	Academic-Local	Medpace	9	Convened	53

Research Team B: Portfolio Complexity Report

Study Identifier	Phase	Sponsor	Status	IRB of Record	CRO	Number of Product	Regulatory Review Level	Total Compexity Score
Trial A	Phase II	Federal	Active	Federal-Central	None	3	Convened	23
Trial B	Phase III	Federal	Active	Federal-Central	None	1	Convened	27
Trial C	Phase II	University	Active	Academic-Local	None	1	Convened	35
Trial D	Phase I/II	University	Active	Academic-Local	None	1	Convened	35
Trial E	Phase I/II	University	Active	Academic-Local	None	1	Convened	35
Trial F	Phase III	Federal	Active	Academic-Local	None	1	Convened	35
Trial G	Phase II	University	Active	Academic-Local	None	2	Convened	35
Trial H	Phase III	Federal	Active	Academic-Local	None	2	Convened	35
Trial J	Phase I/II	University	Active	Academic-Local	None	3	Convened	35
Trial K	Phase II	University	Active	Academic-Local	None	3	Convened	35
Trial L	Phase I/II	Industry	Active	Commercial-Central	None	4	Convened	35
Trial M	Phase I/II	Industry	Active	Commercial-Central	None	5	Convened	35
Trial N	Phase III	Industry	Active	Commercial-Central	None	1	Convened	37
Trial O	Phase I/II	University	Active	Academic-Local	None	5	Convened	37
Trial P	Phase I	University	Active	Academic-Local	None	1	Convened	39
Trial Q	Phase II	Industry	Active	Academic-Local	None	2	Convened	39

Results

- Utilizing stakeholder feedback, a weighting scale was created based on column headers in the figures. Highest (most complex) achievable score is 55 based on the weighting scale.
- A total of 9 complexity reports were created using the reporting function in the e-regulatory system; 2 example complexity reports shown at left.
- Research Team A had a total of 43 studies and average complexity is 33.8.
- Research Team B had a total of 16 studies and average complexity is 34.5.

Discussion / Future Directions

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.
Developing and implementing the system required an intradepartmental collaboration with subject matter experts on creating reports and those who will utilize the reports. Report creators must have a robust understanding of the items which would contribute to regulatory complexity within the specific portfolio. Report users should pair this tool with other tools in the assessment kit such as annual submission metrics to obtain a full scope of understanding for both regulatory complexity and associated submission volume.
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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