Category: Regulatory – Work in Progress

Development and Implementation of a Research Study Regulatory Complexity Assessment Tool

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1. Background

There is an abundant amount of research on complexity of clinical trial design that suggests that clinical trials have become increasingly more complex over the years for a variety of reasons, including recording more patient-reported outcome measures, biomarker studies, and refined eligibility criteria. 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. In the Abramson Cancer Center Clinical Research Unit, Office of Regulatory Affairs (ACC-CRU-ORA), we previously would have to do a manual review of multiple systems to obtain an assessment of research portfolio demographics. In 2019, the ACC-CRU-ORA adopted an e-ISF infrastructure utilizing a commercially available cloud-based document management system. Information about study organizations and product information is a required data point for the study creation in the system. As a result, the ACC-CRU-ORA is now capable of running a report in the system on the composition of the center's research portfolio.

2. Goals

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.

3. Solutions and Methods

Partnering with the vendor and IS collaborators, we leveraged information on the study factors in the cloud-based system to create research team-specific study level reports based on trial phase, study status, and organizations such as IRB of record, regulatory sponsor, CRO, etc. From the report, we implemented a weighting scale from "less" to "most" complex on a regulatory basis and graded each trial in the portfolio accordingly to obtain an overall average assessment of the research portfolio.

4. Outcomes

Leveraging the regulatory complexity assessment tool 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. 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.

5. Lessons Learned and Future Directions

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. 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.

Figure

Study Identifier	Phase	Regulatory Sponsor	IRB of Record	CRO	Number of Products	Regulatory Review Level	Total Complexity Score
UPCC 45416	Phase IV	BMS	WCG IRB	inVentiv Health	0	Expedited	22
UPCC 14422	N/A	Celgene	Advarra IRB	None	0	Expedited	26
UPCC 44417	N/A	Celgene	WCG IRB	ICON	0	Expedited	26
UPCC 56418	N/A	AstraZeneca	Advarra IRB	IQVIA	0	Expedited	26
UPCC A051902	Phase II	Alliance	CIRB	None	14	Convened	31
UPCC 28416	N/A	MSKCC	Penn IRB	None	1	Convened	31
UPCC 04422	N/A	AMC	Penn IRB	None	0	Expedited	32
UPCC 12421	N/A	AstraZeneca	Penn IRB	None	0	Expedited	32
UPCC 32419	N/A	Novartis	Penn IRB	None	0	Expedited	32
UPCC 49419	N/A	Novartis	Penn IRB	None	0	Expedited	32
UPCC 51417	Phase II	ACCRU	Penn IRB	None	5	Convened	37
UPCC E4402	Phase III	ECOG	Penn IRB	None	1	Convened	37
UPCC 15418	N/A	Abbvie	Penn IRB	Analysis Group	0	Expedited	38
UPCC 23414	Phase II	Abbvie	Penn IRB	INCResearch	1	Convened	39
UPCC 22417	Phase III	BMS	Advarra IRB	None	2	Convened	39
UPCC E1912	Phase III	ECOG	Penn IRB	None	5	Convened	41
UPCC 52417	Phase III	Hoffman-La Roche	WCG IRB	Covance	6	Convened	41
UPCC 11411	Phase I/II	University of Pennsylvania-	Penn IRB	None	1	Convened	41
UPCC 02408	Phase II	University of Pennsylvania-	Penn IRB	None	3	Convened	41
UPCC 40419	Phase I	University of Pennsylvania	Penn IRB	None	5	Convened	43
UPCC 59415	Phase II	DTRM	Penn IRB	IQVIA	5	Convened	43
UPCC 20416	Phase III	Merck Sharp	Penn IRB	PPD	2	Convened	43
UPCC 34417	Phase III	Atara Biotherapeutics	Penn IRB	PRAHS	3	Convened	43
UPCC 10418	Phase I/II	PrECOG	Penn IRB	None	2	Convened	45
UPCC 03419	Phase I/II	Forty Seven	Penn IRB	Premier Researc	3	Convened	45
UPCC 09416	Phase II	TG Therapeutics	Penn IRB	None	1	Convened	45
UPCC 43414	Phase III	TG Therapeutics	Penn IRB	None	4	Convened	47
UPCC 53418	Phase III	Novartis	WCG IRB	None	17	Convened	49
UPCC 25415	Phase I/II	TG Therapeutics	Penn IRB	None	6	Convened	49
UPCC 20415	Phase III	Acerta Pharma	Penn IRB	PPD	2	Convened	49
UPCC 22419	Phase I/II	Loxo	Penn IRB	Covance	7	Convened	51
UPCC 11420	Phase II/III	TCR2 Therapeutics	Penn IRB	None	7	Convened	53
UPCC 34418	Phase I	Novartis	Penn IRB	None	6	Convened	53
UPCC 06413	Phase III	Millennium	Penn IRB	ICON	5	Convened	53