Clinical Research Scorecard - Performance Metrics

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1. Background

Strategic clinical research management is integral to advancing the science of cancer care and improving clinical outcomes. Often, enrollment to therapeutic studies is the driving metric for signaling productivity and corresponding justification for resource allocation. However, in cancer clinical research, the complexity and acuity of trials continues to increase with innovative advancements. The Abramson Cancer Center (ACC) Clinical Research Unit (CRU) is currently comprised of 12 research teams that support disease/modality/location specific medical oncology/CAR-T cancer programs within the ACC.

2. Goals

- To advance the overall mission of the ACC CRU by driving enrollment, productivity, and quality, while decreasing deviations and operational inefficiencies
- To develop and maintain standardized key performance indicators (KPIs) that link to purpose
- Evaluate metrics, beyond enrollment, to measure performance and productivity transparently, proactively, and objectively
- To provide targeted progress reporting to optimize resource management, justification, and validation of revolutionized staffing models
- In a snapshot, celebrate what is working well and identify opportunities for improvement

3. Solutions and Methods

ACC CRU central and research team leadership identified and uniformly defined KPIs that aligned with our mission, vision, and values. KPIs included enrollments, time to trial activation, time to first enrollment from study activation, reportable deviations, data completion, auditing and monitoring outcomes, pioneering innovative approaches to clinical research operations, stakeholder feedback, and staff attrition. KPI definitions and source of data were defined across research teams. Each resulting KPI was color coded in a stoplight fashion (green, yellow, red).

Data was compiled and measured for quarterly review by each research team's program manager (PM). In a snapshot, PMs assessed for progress, targeted intervention, and strategic planning opportunities. For example, if a program's enrollments were going up, and data submissions rates were going down; or if enrollments and data submission were doing well, but deviations were on the rise, timely and targeted intervention becomes achievable.

4. Outcomes

The research team's scorecard provided transparent objective metrics to support timely review of the team's clinical research portfolio, overall performance, quality, productivity, and staffing. It streamlined data collection and reporting with related justification for resource utilization, staffing, and evaluation of pilot projects (i.e., hybrid remote work) and associated impact on clinical research operations. And it supported identification of opportunities for improvement and intervention.

5. Lessons Learned and Future Directions

• Engagement with PMs, physician investigators, and study team members is essential

- Must provide uniform reporting source for the objective metrics
- Future directions for 2023:
 - o Adding a KPI for retention
 - o Updating KPI definitions to align with enhanced efficiency post-pandemic

Figure

4	A	В	С	D	E
1	ACC CRU Example Research Team 2022	Q1 (Jan;Feb;March)	Q2 (Apr; May; June)	Q3 (July;Aug;Sept)	Q4 (Oct;Nov; Dec)
2	Mission				
3	Enrollment to Therapeutic Studies	6	10	7	7
4	Total Enrollment	21	30	28	28
5	Time to Trial Activation	190	185	160	130
6	Time to 1st Enrollment from Study Activation	41	20	29	29
7	Values- Stewardship				
8	Studies WITHOUT Any Enrollments	<5%	<5%	<5%	6%
9	Values- Quality & Safety				
10	Reportable Deviations	0	1	0	0
11	Data Completion	94%	80%	85%	90%
12	Audits & Monitoring	Acceptable	Acceptable- Moderate "rating"	Acceptable- Moderate "rating"	Acceptable
13	Values - Innovation				
14	Pioneer New Approaches to Clinical Research Operations	ACC CRU WI	CRN Committee Rep	Spotlight Presentation	CTO Abstract
15	Values- Accountability				
16	Stakeholder Feedback	Investigator Feedback	Collaborative Department	Monitor Feedback UPCC 1234	Investigator Feedback
17	Vision - Engaged Clinical Research Workplace				
18	Attrition	1	0	0	0