

# Clinical Research Scorecard- Performance Metrics

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## BACKGROUND

- Strategic Clinical Research Management is integral to advancing the science of cancer care and improving clinical outcomes.
- Enrollment to therapeutic studies often is the driving metric for signaling productivity and corresponding justification for resource allocation.
- The complexity and acuity of cancer clinical trials continues to increase with innovative advancements.
- The Abramson Cancer Center (ACC) Clinical Research Unit (CRU) is currently comprised of 12 Research Teams (RTs) that support disease/modality/location specific Medical Oncology/CAR-T cancer programs within the ACC.

## 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.

## CLINICAL RESEARCH TEAM SCORECARD

	A	B	C	D	E	
	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	

## SOLUTIONS/ METHODS

- ACC CRU Central and RT Leadership identified and uniformly defined KPIs that aligned with our Mission, Vision, and Values. Each resulting KPI was color coded in a stoplight fashion (Green, Yellow, Red).
- Data was compiled and measured for quarterly review by each RT's Program Manager (PM).
- In a snapshot, PMs assessed for progress, targeted intervention, and strategic planning opportunities.

## OUTCOMES

- Enabled timely identification of opportunities for improvement and intervention.
- Streamlined data and supported justification for resource utilization, staffing, and evaluation of pilot projects (i.e., hybrid remote work) and associated impact on clinical research operations.

## KEY PERFORMANCE INDICATORS (KPIs)- DEFINED

	A	B	C	D	E
1	Key Performance Indicator (KPI)	SOURCE/ REPORT	Green	Yellow	Red
2	Therapeutic Enrollments: 3 month average	SBM/DAG	Enrollment @ Target (>= 2019)	Enrollment (<2019; >2021)	Enrollment (<2021)
3	Total Enrollment: 3 month average	SBM/DAG	Enrollment @ Target (>= 2019)	Enrollment (<2019; >2021)	Enrollment (<2021)
4	Time to activation: average of studies activated in the last 12 months. (Refer to REG-002 SBM Work Instruction for definition and corresponding report in DAG)	SBM/DAG	Average <= 150 days	Average > 150 days ; < 180 days	Average > 180 days
5	Time to 1st Enrollment from Study Activation: within the last 12 months	SBM/ DAG	< 30 days	>30 days; <90 days	>90 days
6	Studies without enrollments: % portfolio studies open to enrollment without any accruals within the last 6 months; excluding dose cohort studies.	SBM/DAG	<5%	>5%, <10%	>10%
7	Reportable Deviations (current quarter)	Regulatory Tracking Log	None	<2	>2
8	Data Completion: % of studies in portfolio without delinquent data (current quarter)	PM ; Sponsor	100-75%	75-50%	>49%
9	Audits & Monitoring: Internal -DOCM; OCR; External Sponsor GCP; FDA (current quarter)	PM	Acceptable "rating"	Acceptable- Moderate "rating"	Any unacceptable "rating"
10	Pioneer New Approaches to Clinical Research Operations : Examples include ACC CRU GD, WIs, Speaker, Spotlight Presentation; Collaborative Department Projects (current quarter)	PM	Yes, completed	Yes, in draft	No
11	Stakeholder Feedback; Including ACC CRU Central - average (current quarter)	PM	Excellent	Making Progress - Moderate	Needs Improvement
12	Attrition (current quarter)	PM	None; staff member >= 2 years	staff member < 2 years; > 15 months	Any staff member <= 15 months

## LESSONS LEARNED / FUTURE DIRECTIONS

- Engagement with PMs, Physician Investigators and RT members is essential.
- Must provide uniform reporting source for the objective metrics.
- Plan to add a KPI for retention.
- Plans to update KPI definitions to align with enhanced efficiencies post pandemic.