Clinical Trial Research Group (CTRG) Guidelines for Trial Portfolio Management

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BACKGROUND

- Clinical investigators are interested in activating the majority of new trial opportunities presented to them and can have a hard time saying no.
- A guideline was needed to help investigators understand how to select and prioritize new trials as well as manage active trials in their portfolios.
- Robust oversight in making trial decisions must account for CTO support/resource limitations, underperforming trials or trials that are no longer as scientifically relevant or serve the patient population. This guideline may also be considered for selection of new trials for activation or closure of existing trials.

METRICS/GOALS

- The goal was to provide a guideline of best practices to each disease area. Some lead by seasoned clinical trialists, some are new leaders.
- Important: Not a policy, mandate, or rule.
- Need flexibility for physician leaders.

METHODS

- Guideline grounded in HCI priority for trials but also support for junior faculty : IITs, CTN, Industry (Phase 1/FIH, Phases 2 and 3), and institutional authorship/accolade.
- Trial accrual to open ratios consider NCI disease prevalence (Figure 1).
- Reviewed and approved by Clinical Research Executive Committee.
- Distributed to CTO Physician Leaders and all CTRG disease groups.

Figure 1

CTRG Ratio – Thresholds based off catchment area and NCI disease incidence.

1. Trial can accrue
   a) At LEAST one+ patients per year or
   b) One patient per year (formally classified rare disease trials)
2. Consider a points-based system to open a trial or close an existing trial.
   a) One (1) point for "Yes" to:
      - IIT studies and/or academic leadership on the steering committee or study chair-ship (important for the CCSG).
      - Trial based on institution's science (important for the CCSG).
      - Fiscally appropriate (specifically IITs and Industry trials are not in deficit).
      - Catchment area cancers (important for the CCSG).
3. Trial will change practice if positive (high impact; a rare disease trial can be practice changing).
4. PI screening and accrual performance across trials in CTRG.
5. Junior investigator (first three years as faculty) leading the trial.

OUTCOMES

- The guide is helpful and consulted regularly at each of disease team meetings as new trials are considered and ongoing trials are reviewed.
- CTRG leaders expressed appreciation for this supportive guideline for their decision-making processes.

Figure 2

CTRG Accrual Ratio, 2021

CTRG Ratio Threshold:	Rate of New Cases/100,000	2021 Ratio*
3	50+/ 100,000	
	Breast	2.80
	Lung	3.00
2.5	20-50/100,000	
	GU	3.13
	Melanoma	2.53
2	10-20/100,000	
	GYN	2.50
	GI	1.10
	H&N	1.47
1.5	0-10/100,000	
	Lymphoma	2.70
	Myeloid/MPN	2.37
	Brain	2.97
	Myeloma	2.60
	Sarcoma	.53

*Ratio is an average of:
1. All Accrual to Open Trials / No. of Open Trials
2. Accruals to Open Trials/ No. of Open Trials (excluding Phase I)
3. Accruals to Open Trials/ No. of Open Trials (excluding Rare Disease)

FUTURE PLANS

- Recommended to use the disease incidence at the states level disease incidence for more applicability to our cancer center catchment area.

Acknowledgements: We appreciate the other cancer centers who contribute to the AACI Listserv.