Category: Trial Start-up and Activation – Work in Progress

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

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1. Background

Clinical investigators are interested in activating the majority of new trial opportunities presented to them and can have hard time saying no. Huntsman Cancer Institute (HCI) has had a high number of new clinical faculty recruited and trained to be principal investigators (PI) in the past several years coupled with a record number of trials that were activated in 2020. The portfolios were becoming saturated, and CTO resources stretched thin. A guideline was needed to help investigators understand how to select and prioritize new trials as well as manage active trials in their portfolio.

2. Goals

The goal was to provide a guideline of best practices, that was not a policy, mandate, or rule, while allowing disease specific flexibility and autonomy by physician leaders.

3. Solutions and Methods

A guideline grounded in the HCI cancer center priority for trials, as well as those that brought investigator authorship or institutional accolade, was implemented April 2021. It included the criteria by which the protocol review and monitoring committee (PRMC) evaluates accrual and/or issues warning letters for poor performing trials (criteria that was not always commonly known by investigators). A clinical trial research group ratio was also developed to show each disease team their unique ratio of new patient accrual performance as compared to the number of open trials they had in a given year. Based off National Cancer Institute (NCI) data of disease incidence, each disease team was placed in an appropriate tiered ratio. The ratio is just one tool to consider in the guideline.

CTRG Guidelines for Trial Portfolio Management:

Robust oversight in making trial decisions should also account for CTO support/resource limitations, underperforming trials, or trials that at no longer as scientifically relevant or serve the patient population. Additional considerations outlined in this guideline may also be considered for careful selection of new trial activation or closure of an existing trial.

CTRG Ratio (thresholds based off catchment area and NCI disease incidence):

1. Trial can accrue
    - *At least* 1+ patients per year, or
    - 1 patient per year (formally classified rare disease trials)
2. Consider a points-based system to open a trial or close an existing trial
    - One (1) point for "Yes" to:
        a) IIT studies and/or academic leadership on the steering committee or study chair-ship*
        b) Trial based on institution's science*
        c) Fiscally appropriate (specifically, IITs and industry trials are not in deficit)
        d) Catchment area cancers based on Utah incidence* (including breast, prostate, melanoma, colorectal, lung, leukemia
        e) Trial will change practice if positive (high impact; a rare disease trial can be practice changing)
        f) PI screening and accrual performance across trials in CTRG

g) Junior investigator (first three years as faculty) leading the trial

**Important for CCSG*

The guideline also included the criteria by which the PRMC evaluates accrual and/or issues warning letters for poor performing trials. The criteria by which the PRMC evaluated trial performance was not commonly known by investigators.

4. Outcomes

The guide is helpful and consulted regularly at each of disease team meetings as new trials are considered and ongoing trials are reviewed.

5. Lessons Learned and Future Directions

It was recommended that rather than use the disease incidence rate nationally, this be revised to be the state level disease incidence for more applicability to our cancer center catchment area.

Figure:

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)