Category: Quality Assurance, Remote Monitoring, and Auditing – Work in Progress

Standardized Quality Metrics in Cancer Clinical Trials: A Qualitative Study

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1. Background

Cancer trials are lacking any universal metrics that are outside of study timelines and start-ups. It is difficult for a clinical trials office (CTO) to measure the safety and efficacy within the department. Finding how quickly a study was started or number of patient accruals is easy, however there is no universal data to show the safety of the study and the safety of the procedures behind the scenes in the CTO that support patient safety.

The general problem to be addressed is the lack of universalized quality and safety metrics for clinical trials cancer research (outside of study timelines) resulting in the inability for health care organizations to measure safety, performance, and improve expenditures.

2. Goals

Answer these questions:

1. Why is there a lack of measurable research metrics within cancer clinical trials outside of study timelines?
    a. What contributes to the lack of measurable research metrics?
    b. What actions could cancer clinical trials participate in to encourage measurable metrics outside of study timelines?
2. Why aren't there ways to measure a cancer clinical trials organization's achievement?
    a. What metrics can be measured to assess fiscal impacts on a CTO?
    b. What metrics can be measured to assess safety of a trial?
    c. What are the drivers for achievements within cancer research performance metrics?
3. What cultural elements are present in cancer research clinical trials that prevents collaboration and universalized standards?

3. Solutions and Methods

We believe the qualitative design with a flexible rationale is the most appropriate method because the problem statement will be focused on qualitative research, (i.e., finding out why there aren't measurable research metrics in cancer clinical trials). When researching the "why" it will also be important to show what is available now. This will be a grounded theory, historical study, and action research study. With thorough data analysis and the theory of successful universal metrics in cancer research, followed by review of historical studies and the action of potential improvements.

4. Outcomes

We will use a heatmap that consists of a standard deviation between common categories in clinical trials to measure outcomes. This is a work in progress and more outcomes, benchmarks, key drivers, and categories will be added to encompass all the data we seek to gather. (See Figure.)

5. Lessons Learned and Future Directions

To understand why we don't have metrics already in place we need to know the history behind clinical trials (Jones et al., 2020; Walter et al., 2021).

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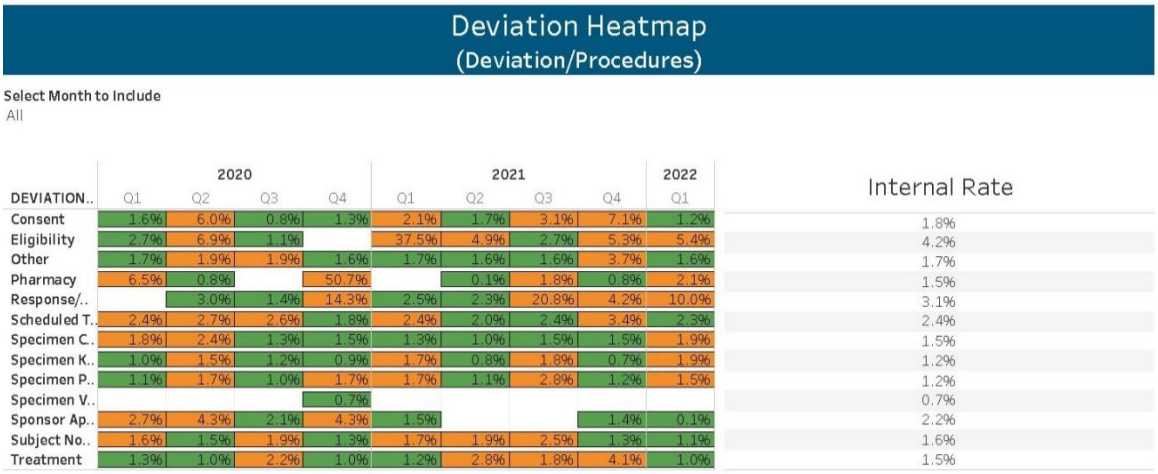
To form the opinion of the importance of measurable metrics outside of clinical trial study timelines this question is important to build a foundation on the importance of measuring these (Smith et al., 2018). Being able to answer what metrics would measure safety and fiscal impacts and learning what drives these outcomes can help find where the implementation needs to begin (Walker et al., 2018).

Finally, it will be important to address the culture that is found within clinical trials.

Figure:



	2020				2021				2022	
DEVIATION..	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Internal Rate
Consent	1.6%	6.0%	0.8%	1.3%	2.1%	1.7%	3.1%	7.1%	1.2%	1.8%
Eligibility	2.7%	6.9%	1.1%		37.5%	4.9%	2.7%	5.3%	5.4%	4.2%
Other	1.7%	1.9%	1.9%	1.6%	1.7%	1.6%	1.6%	3.7%	1.6%	1.7%
Pharmacy	6.5%	0.8%		50.7%		0.1%	1.8%	0.8%	2.1%	1.5%
Response/..		3.0%	1.4%	14.3%	2.5%	2.3%	20.8%	4.2%	10.0%	3.1%
Scheduled T..	2.4%	2.7%	2.6%	1.8%	2.4%	2.0%	2.4%	3.4%	2.3%	2.4%
Specimen C..	1.8%	2.4%	1.3%	1.5%	1.3%	1.0%	1.5%	1.5%	1.9%	1.5%
Specimen K..	1.0%	1.5%	1.2%	0.9%	1.7%	0.8%	1.8%	0.7%	1.9%	1.2%
Specimen P..	1.1%	1.7%	1.0%	1.7%	1.7%	1.1%	2.8%	1.2%	1.5%	1.2%
Specimen V..				0.7%						0.7%
Sponsor Ap..	2.7%	4.3%	2.1%	4.3%	1.5%			1.4%	0.1%	2.2%
Subject No..	1.6%	1.5%	1.9%	1.3%	1.7%	1.9%	2.5%	1.3%	1.1%	1.6%
Treatment	1.3%	1.0%	2.2%	1.0%	1.2%	2.8%	1.8%	4.1%	1.0%	1.5%