Establishment of a Zero Tolerance Policy to Eliminate Non-Performing Studies

Thomas George, MD, FACP; Alison Ivey, RN, MS, OCN, CCRP; Ashley Anderson, MBA, ACRP-CP; Timothy Guinn, MSHCA, CCRP

BACKGROUND

The UFHCC Scientific Review and Monitoring Committee (SRMC) is tasked with review of all cancer relevant research studies conducted at the University of Florida (UF). The UFHCC Clinical Research Office (CRO) is primarily responsible for ensuring accurate protocol and accrual status entry within the Clinical Trials Management System (CTMS), OnCore, and notifying investigators of studies that are failing to meet minimum accrual benchmarks.

Investigators and/or Disease Site Groups (DSGs) have long struggled with finding a balance between interesting science and feasibility of accrual resulting in portfolios that are misaligned with their patient population. The tax of resources to maintain trials (staffing, IRB support, contractual work, etc.) at a large academic cancer center, requires continuous review to ensure appropriate stewardship of limited resources.

Evaluation of historic data illustrates that studies which fail to accrue within the first six months of site activation are unlikely to ever reach a successful completion.

GOALS

- Systematic closure of non-performing trials to allow for re-deployment of assigned resources
- Robust deliberations for trial selection within DSG portfolios, focusing on current patient needs and feasibility of trials

SOLUTION & METHODS

In 2018, the SRMC developed the **Zero Tolerance Policy** to target interventional trials with no accrual activity.

The initial implementation of the policy called for closure of a study if there were no patient accruals by 12 months post-activation. This policy was subsequently strengthened, placing studies on administrative probation at 3 months and requiring termination at 6 months if accrual remains at zero.

As part of the probation process, the study undergoes a new feasibility review to determine if the appropriate patient population exists and if new recruitment strategies could be implemented. Investigators are also required to craft a Corrective Action Plan based on the feasibility findings.

If the corrective actions fail, studies are administratively terminated by the SRMC if they are not electively closed by the investigator or DSG. All administrative terminations by SRMC through this policy are final and without an opportunity for appeal.

Exemptions from this policy include studies involving a rare disease (modified NIH definition), pediatric trials, highly-selected IITs and studies experiencing moderate, but temporary, closures to accrual.

CONTACT

Alison Ivey, RN, MS, OCN, CCRP
Administrative Director
University of Florida Health Cancer Center
2033 Mowry Road, Rm 395
Gainesville FL 32610
(352) 294-8567 • aivey@ufl.edu

OUTCOMES

- Implementation of the Zero Tolerance Policy resulted in a higher percentage of studies placed on probation in 2018 compared to 2017 (37% vs 20%).
- The number of studies closed with zero accrual in 2018 rose by 30% over the previous year.
- Due in part to this policy, the initial feasibility review process has become more robust and data driven.
  - The CRO subsequently established metrics to assess available patients in light of investigator stated accrual goals.
  - The ratio of available patients to target accrual is now a key part of the feasibility review process.
  - Clear expectations for immediate study enrollment is now pervasive across the UFHCC with the Zero Tolerance Policy credited with establishing this culture.

FUTURE DIRECTIONS

Future directions include incorporating the UFHCC Community Outreach and Engagement (COE) Director in initial and probationary reviews of trials to determine if there are opportunities to enhance recruitment via COE resources and expanding the administrative closure policy to poorly, but not zero, performing studies.