Category: Finance/CCSG/PRMS – Completed Project

Impact of the SRMC Zero Tolerance Policy on DSG Trial Portfolios

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1. Background

In 2018, the University of Florida Health Cancer Center (UFHCC) scientific review and monitoring committee (SRMC) implemented a zero tolerance policy (ZTP), to raise enrollment expectations among the disease site groups (DSG). The ZTP requires administrative closure of studies without any enrollment within 6 months following activation as historic data demonstrate these studies are unlikely to succeed. The goals of the ZTP are twofold: to lessen the resource burden to maintain trials, and to encourage better trial selection. Once implemented, the policy had differential impacts across UFHCC's 13 DSGs. While several groups flourished under the policy with well-rounded trial selection, some portfolios were greatly reduced, requiring awareness of trial availability outside of their DSG. Additionally, a growing number of rare and pediatric studies were granted exemptions and allowed to continue without accruing for several years.

2. Goals

- Closure of non-performing trials to allow for re-deployment of assigned resources
- Performance metrics of DSG portfolios, focusing on patient needs and feasibility of trials

3. Solutions and Methods

The ZTP targets interventional trials with no accrual activity. Initially demonstrating success by closing studies with 0 accruals by 12 months post-activation, it was subsequently strengthened, placing studies on administrative probation at 3 months and terminating at 6 months if accrual remained at 0. During probation, feasibility is re-assessed to confirm patient population availability, and new recruitment strategies are devised by the clinical research office in conjunction with the community outreach and engagement (COE) office. Investigators must synthesize this information and choose to close the study or submit a corrective action plan (CAP) addressing enrollment. If the CAP fails, studies are administratively terminated per the ZTP and there is no process for appeals.

Previous exceptions to this policy included rare disease studies (modified NIH definition); pediatrics; high-priority investigator-initiated trials; national trials led by UF faculty; and studies experiencing moderate, but temporary, enrollment suspensions. Seeing a rise in study exemptions, the policy was updated in 2021, closing this loophole and requiring that previously exempted trials enroll within 2 years or face termination.

4. Outcomes

The ZTP reduced the number of studies placed on probation. Studies placed on probation initially increased by 16 percent (22 percent vs. 38 percent) between 2017 and 2018, whereas from 2019-2021, only 23 percent of studies reviewed were placed on probation. However, the number of studies closed with 0 accrual in 2021 rose by 27 percent over the previous two years, largely due to the 2021 policy changes.

The ratio of available patients to target accrual is now a key part of the feasibility assessments, with clear expectations for early study enrollment shared across the UFHCC. This has allowed many DSGs

with diminished disease specific study portfolios to focus and increase enrollment onto disease agnostic studies managed by our early-phase and disease agnostic DSG.

5. Lessons Learned and Future Directions

The ZTP improved stewardship of limited resources and provided DSGs with opportunities to better align with patient needs. Future directions include incorporating the COE director for more exhaustive discussions during initial protocol reviews for enhanced recruitment opportunities via COE resources. DSGs and investigators are now better prepared to align studies with patient needs, minimizing wasted resources with non-performing studies.

Figure: