Impact of the SRMC "Zero Tolerance" Policy on DSG Trial Portfolios

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BACKGROUND

In 2018, the UFHCC Scientific Review and Monitoring Committee (SRMC) implemented the Zero Tolerance Policy (ZTP), to improve Disease Site Groups (DSG) enrollment accountability. The ZTP requires administrative closure of studies without any enrollment at 6 months following activation as historic data demonstrates these studies are unlikely to succeed. The goals of the ZTP are twofold; lessen the resource burden to maintain trials and 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 two years.

GOALS

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

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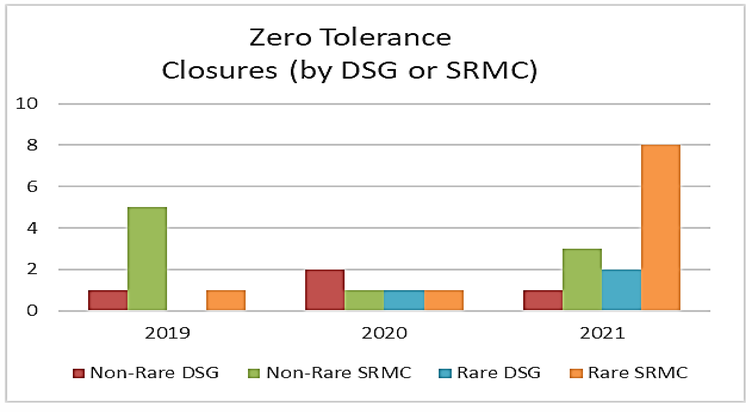
METHODS

The ZTP targets interventional trials with no accrual activity. Initially demonstrating success by closing studies with zero accruals by 12 months post-activation; it was subsequently strengthened, placing studies on administrative probation at 3 months and terminating at 6 if accrual remained zero. 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. There is no process for appeals.



Previous exceptions to this policy included rare disease studies (modified NIH definition), pediatrics, high-priority IITs, 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.

RESULTS

The ZTP reduced the number of studies placed on probation. Studies placed on probation initially increased by 16% (22% vs 38%) between 2017 and 2018 whereas from 2019-2021, only 23% of studies reviewed were placed on probation. However, the number of studies closed with zero accrual in 2021 rose by 27% over the previous 2 years, largely due to the 2021 policy changes for rare disease studies.

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.

FUTURE DIRECTIONS

The ZTP has improved stewardship of limited resources and provided DSGs with opportunities to better align with patient needs, with clear administrative accountability. 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.