# FAST-TRACK PILOT PROGRAM

Jacqueline Quivers, MS[1,2]; Erin Williams, MBA [1,2]; Angelia Riley, MSHS[1,2]; Yolanda Pitts, M.Ed[1,2]; Diadria Thomas, BS[1,2]; Christye Farrell, AGS[1,2]; Doreen Rodriguez, BBA[1,2]; Vijayalakshmi Poleboina, M.Pharm[1,2]; Sharon Issac, MS[1,2]; Joshua Kern, BS[1,2]; Luyen Thai, MS[1,2]; Scott Holdridge, MBA[1,2]; Tian Zhang, MD, MHS[1,2,4]; Asal Rahimi, MD, MS[1,2,3]

[1.] Harold C. Simmons Comprehensive Cancer Center, The University of Texas Southwestern Medical Center, Dallas, TX; [2.] University of Texas Southwestern Medical Center, Dallas, TX; [3.] Department of Radiation Oncology, University of Texas Southwestern Medical Center, Dallas, TX; [4.] Division of Hematology and Oncology, Department of Internal Medicine, University of Texas Southwestern, Dallas, TX

UT Southwestern Simmons Cancer Center

## INTRODUCTION

Efficient clinical trial activation is crucial for timely patient access to innovative therapies and maintaining a competitive research environment. However, activation timelines are often prolonged due to regulatory approvals, budget and contract negotiations, and administrative bottlenecks. Downstream consequences include increased expense, suboptimal accrual, move of clinical trials overseas and delayed availability of treatments for patients.[1] To address these challenges, the fast-track pilot program was initiated to streamline activation for select studies while ensuring compliance and quality standards.

## OBJECTIVE

The fast-track initiative aims to activate clinical trials within 60-90 days from Protocol Review and Monitoring Committee (PRMC) submission. This is achieved through optimized workflows, parallel processing, streamlined communication tools, and enhanced stakeholder coordination. By identifying and mitigating common delays, the program accelerates the transition from site selection to patient enrollment.

## ACKNOWLEDGEMENTS

We would like to thank the UT Southwestern Human Research Protection Program, the Subcommittee for Human Use of Radiation, Sponsored Programs Administration, and Investigational Drug Services for their support and collaboration throughout this project.

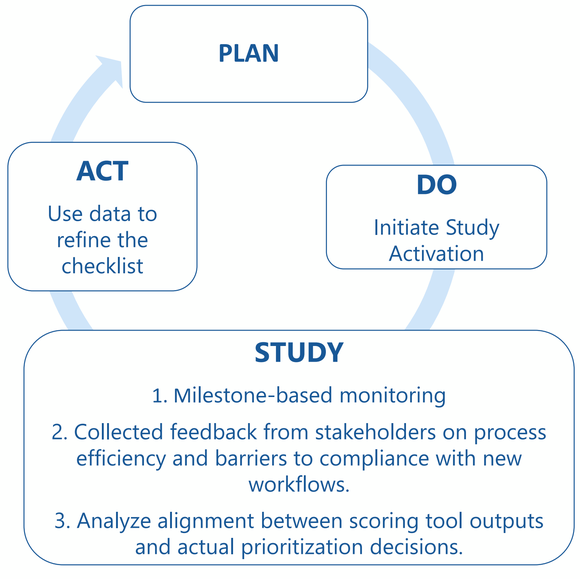
## METHOD

Create a **pre-submission checklist** ensures all regulatory documents and templates (e.g., final protocol, budget, contract templates, study manuals) are available in advance

Create a scoring tool to prioritizes studies based on alignment with Cancer Center.

Formation of a dedicated Fast-Track team to facilitate early engagement with key internal stakeholder collaboration

Stakeholder meeting: Internal and external collaboration was established to set clear expectations for expedited document exchanges, reviews, and approvals.




## RESULTS

Since implementation, eight (including seven industry-sponsored) studies have completed the fast-track process, achieving a median activation time of 83 calendar days, an improvement from the previous median of 147 calendar days in 2023 (and compared to 181 for industry-sponsored studies).

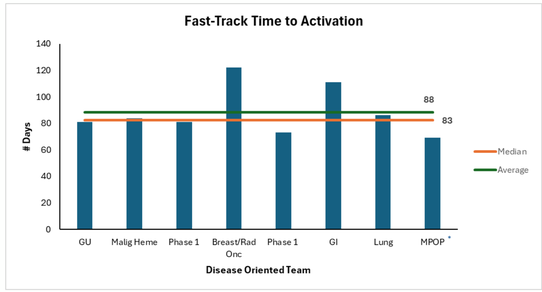



***Figure 3**. Highlights the median and average time to activation for the studies that entered the Fast-Track program.*

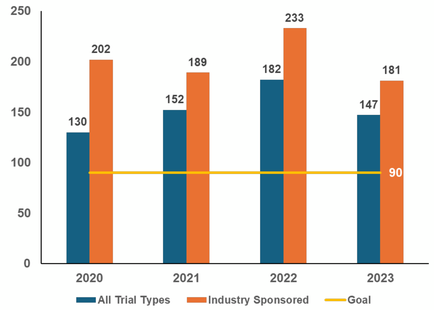



***Figure 4**: Overall time to activation per year.*


***[*] Figure 5**: Fast track timeline for Multi Precision Oncology Program (MPOP) Disease Oriented Team.*

## CONCLUSION

The fast-track process has significantly reduced median study activation time positioning the site as a leader in activation and enrollment. Success depends on close coordination between the sponsor and study team, with delays often stemming from misalignment. To maintain progress, timely informed consent and budget reviews, early FDA approvals for investigator-initiated studies, and advance site initiation visit (SIV) scheduling are essential. Continued adherence to these practices will support faster access to life-saving treatments.

## REFERENCES

1. Watters, J. T., Pitzen, J. H., Sanders, L. J., Bruce, V. M., Cornell, A. R., Cseko, G. C., Grace, J. S., Kwon, P. S., Kukla, A. K., Lee, M. S., Monosmith, M. D., Myren, J. D., Kottschade, R. S., Shaft, M. N., Weis, J. A., Welter, J. C., & Bharucha, A. E. (2017). Transforming the activation of clinical trials. *Clinical Pharmacology & Therapeutics*, *103*(1), 43–46. https://doi.org/10.1002/cpt.898

## CONTACT INFO

**Jacqueline Quivers, MS**
Associate Director, SCCC Clinical Research Office
University of Texas Southwestern Medical Center – H. Simmons Comprehensive Cancer Center
Email: jacqueline.quivers@utsouthwestern.edu