Utilization of Dual PI Model for Non-Oncology CAR-T Clinical Trials at Standalone and Matrix Cancer Centers: Best Practices from Moffitt Cancer Center and Meyer Cancer Center at Weill Cornell

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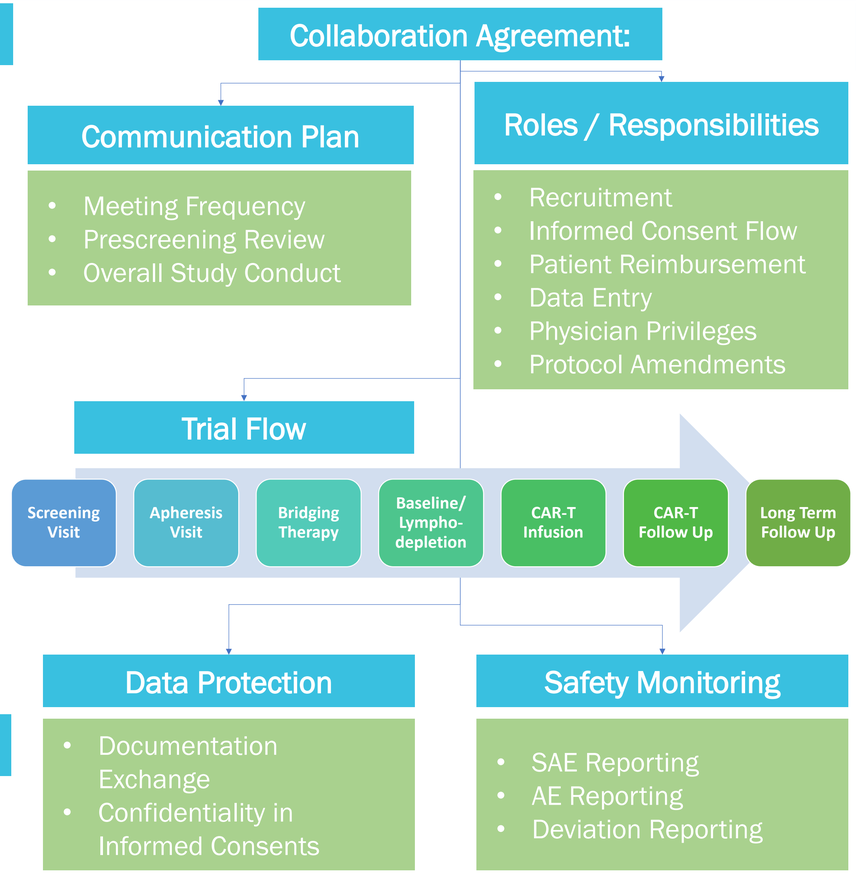
Background

- Non-oncology CAR-T trials require multi-institutional and cross-specialty collaboration to execute successfully.
- These studies face unique operational complexities, including shared clinical oversight, complex consent processes, and need standards established for billing, budgeting, and contracting across institutions.
- Traditional single-PI leadership models fail to integrate the diverse expertise needed to manage CAR-T–specific toxicities alongside non-oncology disease-specific care requirements.
- New collaborative governance frameworks are needed to align scientific direction, operational execution, and institutional accountability in non-oncology CAR-T trials.

Goals

- Pilot a Dual PI model with two disease-specific PIs from different sites providing full oversight under a single protocol.
- Evaluate the feasibility and effectiveness of the Dual PI model for non-oncology CAR-T trials.
- Define the operational support and infrastructure required to successfully conduct Dual PI, multi-site, non-oncology CAR-T studies.
- Develop best practices for operational excellence, budgeting and contracting, informed consent process, and safety oversight that ensure regulatory compliance and patient safety.



Outcomes and Real-World Experience

- Trial Activation Milestones:
  <u>Moffitt Cancer Center:</u>
  - First activation: November 2025
  - Second activation: February 2026

  <u>Meyer Cancer Center:</u>
  - First activation: October 2025
- Meyer Cancer Center treated the first patient under this model on 3/10/2026.

Solutions and Methods

- Implemented the Dual PI model that integrates disease-specific expertise with cellular immunotherapy oversight to support non-oncology CAR-T trials.
- Explored and refined budgeting and contracting approaches.
- Established streamlined consent workflows, including dual-consent processes across institutions.
- Formalized operational collaboration frameworks, covering shared staffing models, adverse event and deviation reporting, and data management.

Lessons Learned and Future Directions

- The collaboration agreement provided essential guidance and was frequently consulted throughout the first participant's treatment course.
- Open, consistent communication between sites was essential to prevent protocol deviations.
- Continuous coordination was essential for moving the participant through each phase of the study without delays.
- Identifying a primary participant contact earlier in the process will improve clarity for future participants and avoid confusion.

<u>Continue to standardize:</u>

- Collaboration agreements between sites
- Framework for billing classification and fee schedules
- Cross-disciplinary CAR-T educational resources
- Consent, budgeting, contracting, and data-sharing workflows