Category: Cross-cutting Innovation and Collaboration – Work in Progress

Non-Malignant Cell Therapy Integration and Collaboration with Cancer Research at an Academic Medical Center

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1. Background

Immune effector cell therapy (IEC) has revolutionized hematology, particularly in the treatment of hematologic malignancies, and more recently in solid tumors. While cell therapy has predominantly focused on malignant diseases, recent clinical research has been exploring its applicability in non-malignant conditions. At the University of Kansas, our cancer center and non-malignant research teams are partnering to conduct clinical trials in indications in rheumatologist and neurologic immune mediated disorders.

2. Goals

Our Division of Hematologic Malignancies and Cellular Therapeutics (HMCT) program, in collaboration with cancer center research and non-malignant research teams, aimed to establish a standardized framework for interdisciplinary collaboration, ensuring seamless integration and effective delivery of these therapies between research team members and clinical staff.

3. Solutions and Methods

Capacity Planning: Cellular therapy trial capacity is determined annually by our IEC Steering Committee using shared resourcing knowledge and accrual projections.

Trial Intake and Feasibility: While our cancer and non-malignant study, regulatory, and finance teams are separate groups, a centralized Cellular Therapy Site Development team supports feasibility assessments for all cell therapy studies. If proceeding, the study team submits protocol documents and requests a centralized IEC Disease Working Group (DWG) review.

Planning and Approval: IEC DWG determines institutional interest and HMCT management level (Minimal vs. Shared). To promote collaboration a Co-Investigator from HMCT is assigned for non-malignant cell therapy trials. Further review by the Immune Effector Cell Investigational Review Committee (IECIRC) ensures workflow development and readiness for all cell therapy trials.

Upon IECIRC approval an educational packet is provided to the study team, including a standard operating procedure (SOP) outlining processes, and regulatory resources.

Enrollment Process: Once a patient is identified, the research team secures consent and confirms eligibility. A standardized email template is used across cancer and non-malignant research teams to communicate newly enrolled participants.

Infusion and Follow-up: Research staff and cellular therapy nurses manage protocol requirements, including hospitalization if needed. Post-infusion follow-up varies based on involvement level: Minimal Involvement: HMCT support is limited to apheresis/cell processing services; follow-up remains with the primary research team.

Shared Management: Bone marrow transplant (BMT) IEC nurse coordinators schedule chemo, cell infusions, and post-discharge follow-ups within the cancer service line and treatment areas. Patients are managed by HMCT until Day +28 in collaboration with the primary team, after which stable patients return to the primary disease program.

This framework enhances collaboration, ensures proper oversight, and streamlines the integration of non-malignant immune effector cell therapies into clinical practice.

4. Outcomes

Six cell therapy trials for non-malignant indications have been activated, accruing eight patients. Startup is progressing on eight additional studies. The Cellular Therapy Site Development team has collaborated with six different primary research teams using this framework. Initial feedback from the teams has been positive, with research teams saying they feel supported in these complicated trials.

5. Learned and Future Directions

The integration of non-malignant teams into cell therapy research requires additional support and structured collaboration.

Study-specific workflows help clarify roles but need continuous refinement for efficiency.

Regular, structured communication between HMCT and non-malignant teams enhances coordination and trial execution.