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

THE UNIVERSITY OF KANSAS CANCER CENTER

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Background:

While cell therapy has predominantly focused on malignant diseases, recent **clinical research** has been exploring its applicability **in non-malignant conditions**

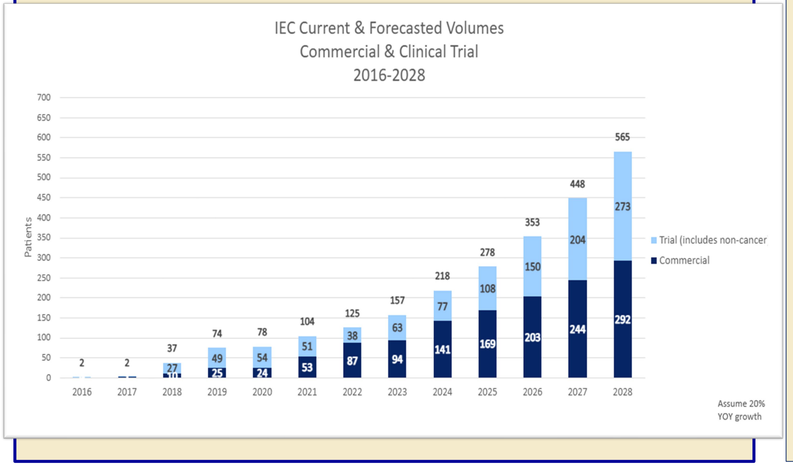
Goals:

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

Solutions and Methods:

Capacity Planning

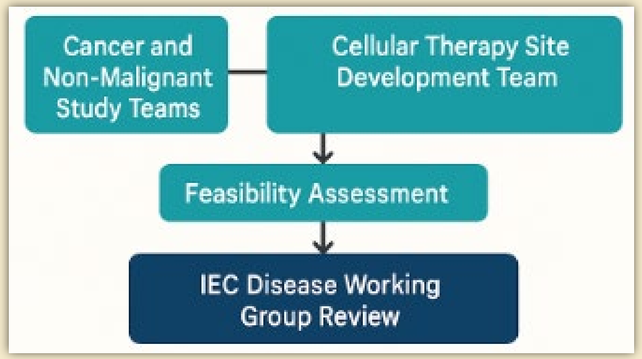
Cellular therapy trial capacity is determined annually by using shared resourcing knowledge and accrual projections.



Solutions and Methods (continued):

Centralized 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



Planning and Approval

IEC DWG determines institutional interest and HMCT management level (Minimal vs. Shared). 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.

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:** 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.

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.

Lessons 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

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