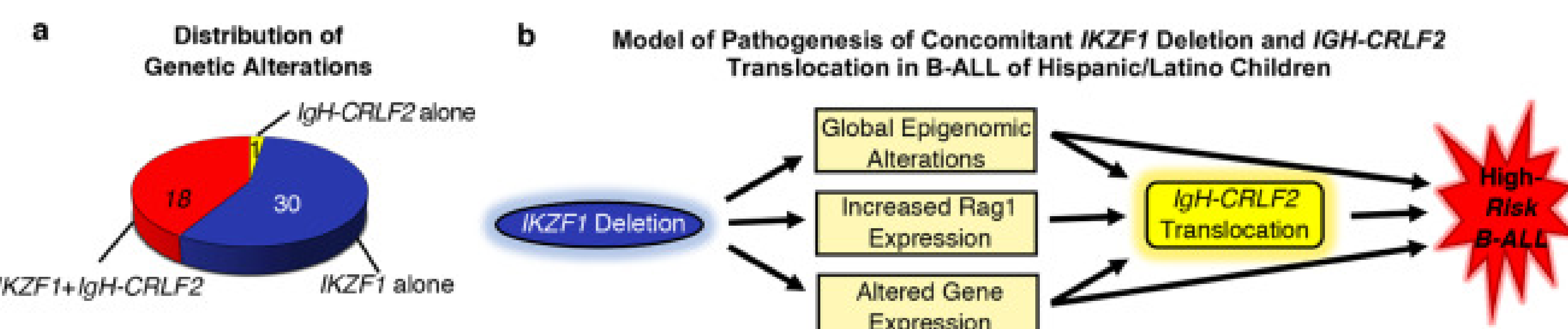


Hisham Abdel-Azim, MD, MS  
Director

## Featured Publications

### Increased Incidence of IKZF1 deletions and IGH-CRLF2 translocations in B-ALL of Hispanic/Latino children—a novel health disparity

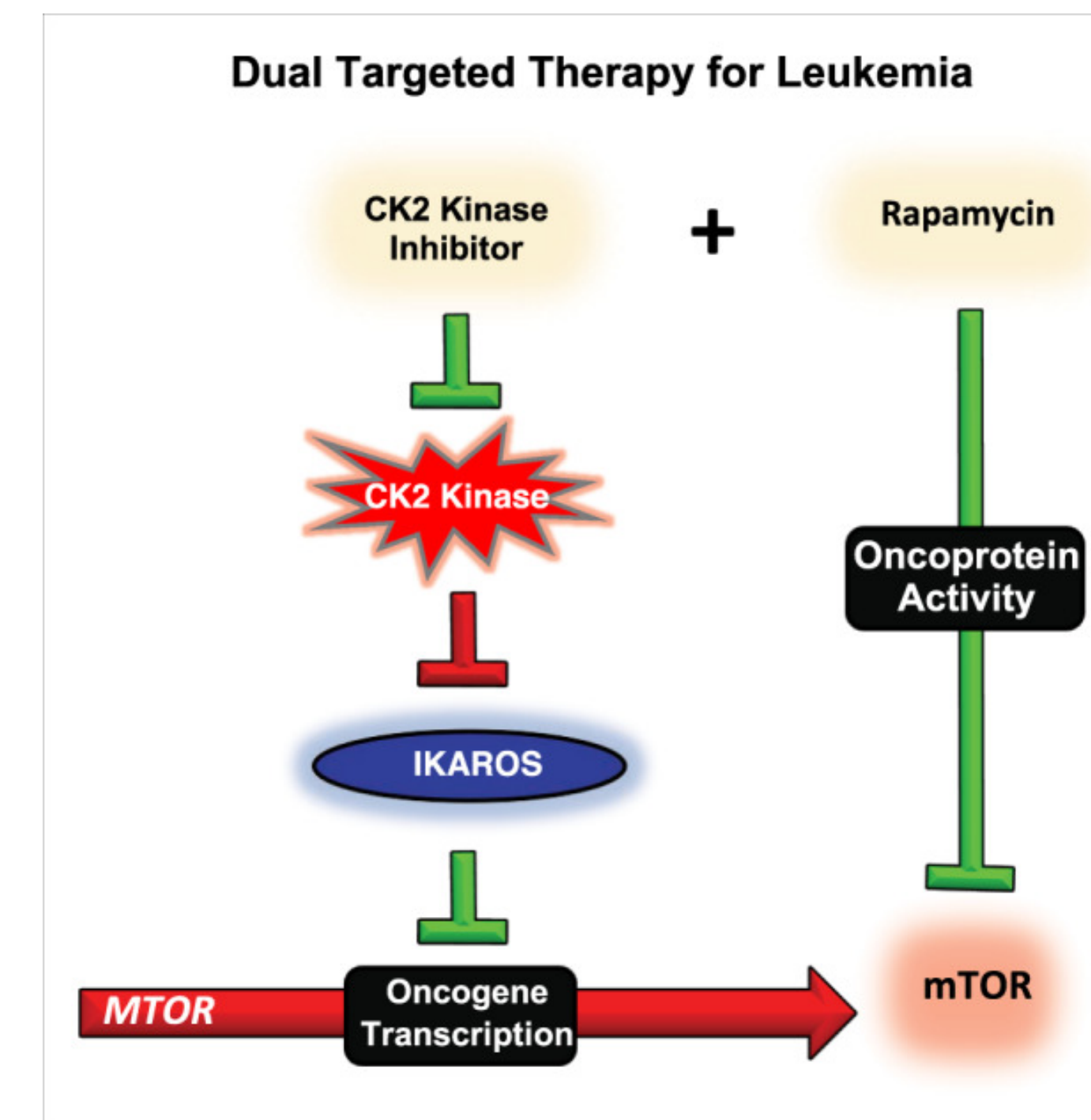
Raca G, Abdel-Azim H, Yue F, Broach J, Payne JL, Reeves ME, Gowda C, Schramm J, Desai D, Dovat E, Hu T, Berg AS, Bhowani D, Payne KJ, Dovat S. *Leukemia*. 2021 Aug;35(8):2399-2402.



**a** Relationship between IKZF1 deletion and IGH-CRLF2 translocation in B-ALL of Hispanic/Latino children. **b** Model of pathogenesis of concomitant IKZF1 deletion and IGH-CRLF2 translocation in B-ALL of Hispanic/Latino children.

### Dual targeting of MTOR as a novel therapeutic approach for high-risk B-cell acute lymphoblastic leukemia

Ge Z, Song C, Ding Y, Tan BH, Desai D, Sharma A, Gowda R, Yue F, Huang S, Spiegelman V, Payne JL, Reeves ME, Iyer S, Dhanyamraju PK, Imamura Y, Bogush D, Bamme Y, Yang Y, Soliman M, Kane S, Dovat E, Schramm J, Hu T, McGrath M, Chroneos ZC, Payne KJ, Gowda C, Dovat S. *Leukemia*. 2021 May;35(5):1267-1278



### Relapse Risk for B-ALL Patients by Pre-Hematopoietic Cell Transplantation (HCT) Next-Generation Sequencing (NGS-MRD): An Interim Analysis of Observational Arm Subjects on Pediatric Transplantation and Cellular Therapy Consortium (PTCTC) ONC1701

Quigg TC, Skiles JL, Keating AK, Mahadeo KM, Salzberg D, Madden LM, Phelan R, Lalefar N, Caywood E, Hanna R, Bhatt ST, Stefanski HE, Horn B, Oshrine B, Higham CS, Duffner UA, Chewing JH, Law J, Shah NC, Huo J, Lehmann LE, Ahmed I, Pulsipher MA, Hisham Abdel-Azim. *Transplant Cell Ther*. 2022 Feb 15:S2666-636

Figure 1. Pre-HCT NGS-MRD and BCR+ vs BCR- Outcomes

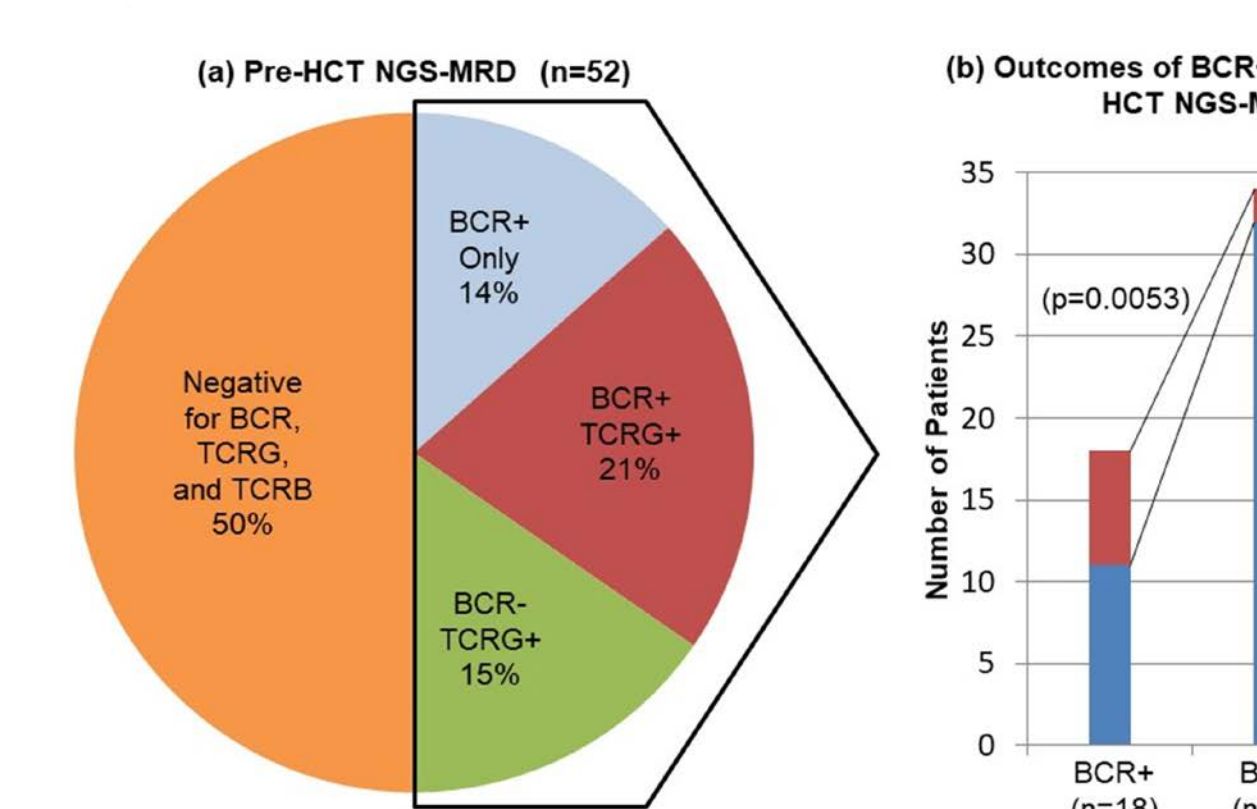
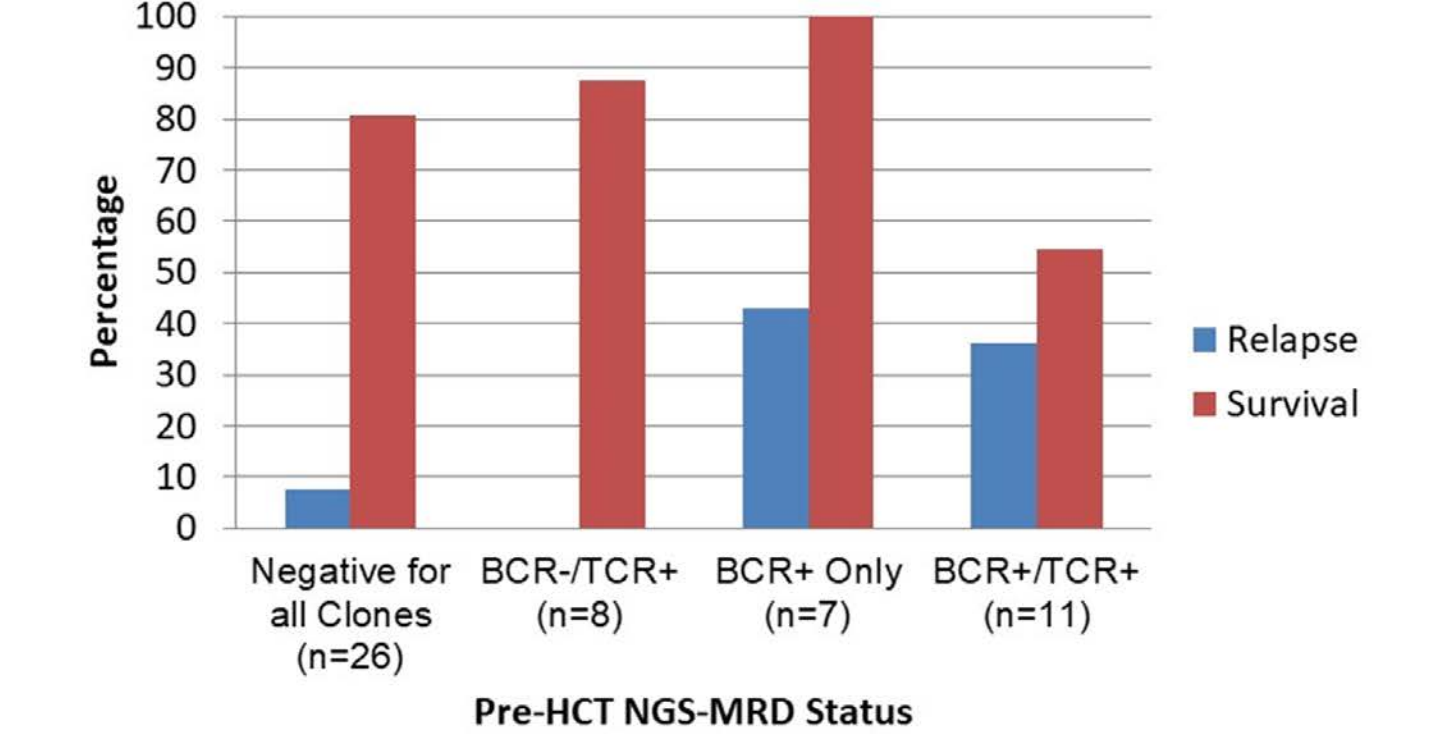


Figure 2. Post-HCT Relapse and Survival Rates by Pre-HCT NGS-MRD Status



## Vision for Integrated Cell Therapy

### Goals

- Increase availability of cell therapies for large and diverse patient population with special focus on including *diverse and high-disparity communities* for children, adolescents and adults
- Recruit additional scientific leadership, investigators and multidisciplinary team of experts
- Enhance state-of-the-art infrastructure TCT & GMP lab
- Leadership in cell therapies mainly **across cancer applications (hematological and solid cancers)** in addition to non-cancer applications including regenerative medicine
- Ability to engineer graft from blood cells and other tissues

## Cell Therapy Related Applications Across Disciplines

- Gene therapy for SS disease, SCID, Thal and other non-malignant conditions
- Immune tolerance after solid organs transplant
- Diabetes
- Anti-viral CTLs production
- Burns, skin damage, cartilage and muscle repair
- Enteric neuropathies, short bowel syndrome, inherited metabolic liver disease
- Macular degeneration, inherited retinal degenerations
- Bone repair, bony defects, non-healing fractures
- kidney repair and regeneration
- Cell-based diagnostic and therapeutic agents
- Alzheimer's disease neuronal stem cells experimental applications

## TCT and GMP Lab

### Mission

The Transplant and Cell therapy (TCT) and Good Manufacturing Practices (GMP) lab at LLUMC is created to produce safe and effective novel cellular component therapy that meets regulatory guidelines for clinical use and facilitates research to be translated from the bench to the bedside

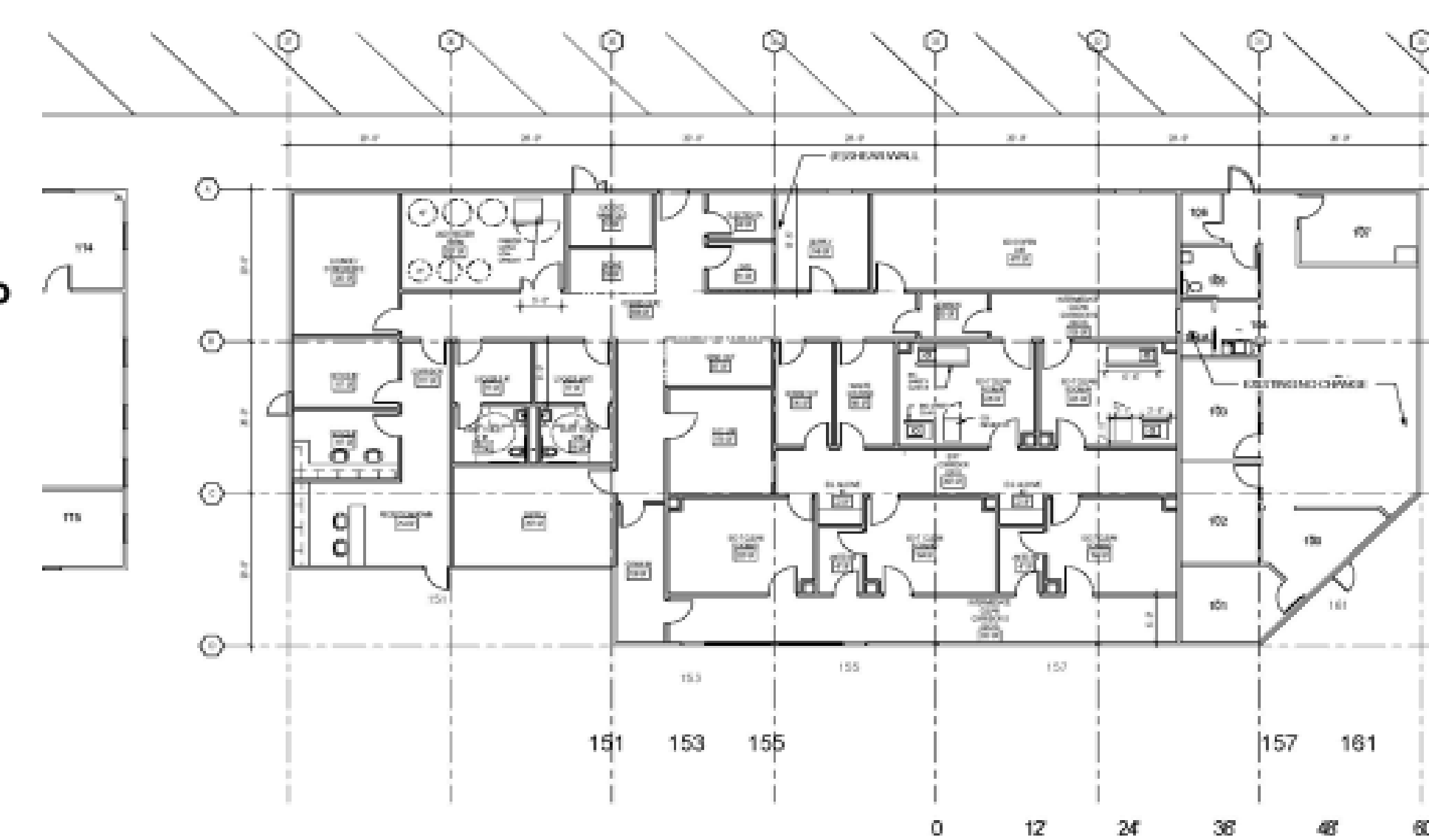
The goal of this facility is to assist investigators in developing new cell-based therapies mainly for cancer and also for non-cancer applications to support clinical research studies designed to evaluate the toxicity and efficacy of these novel treatments

The lab is dedicated to the production of clinical grade cellular products for patients who participate in clinical trials conducted by LLU investigators

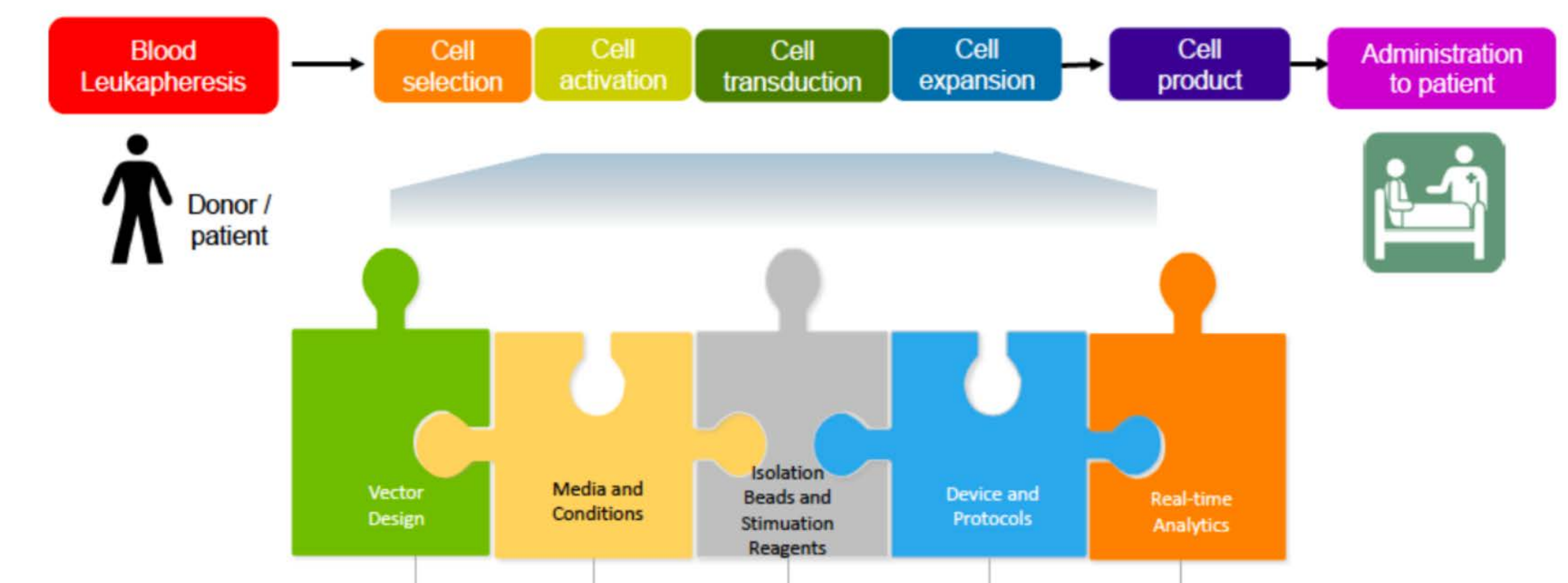
The TCT and GMP lab is available resource to both clinical and laboratory investigators at LLU

### New HPC/cGMP Facility Under Development-LLU

- 5,000 gross square feet in
- five ISO 7 clean rooms for handling of materials from different patients
- one has a separate anteroom to allow gene therapy vector manufacturing;
- an ISO 8 closed system multi-product manufacturing room;
- an ISO 8 gowning room and clean corridor



## Example for Cell Therapy Manufacturing Process



## Summary

### Transplant and Cell Therapy Division

Perform all cellular cancer therapies across LLUH including pediatric and adult patients:

- Bone marrow transplant
- CAR-T cell therapies
- Other immune cellular therapies
- Other experimental cellular therapies

Perform early phase cellular therapy clinical collaborative research with emphasis on cancer

Multi-disciplinary role in progressing translational cellular therapy from bench to bedside

Pivotal role toward LLU comprehensive Cancer Center designation