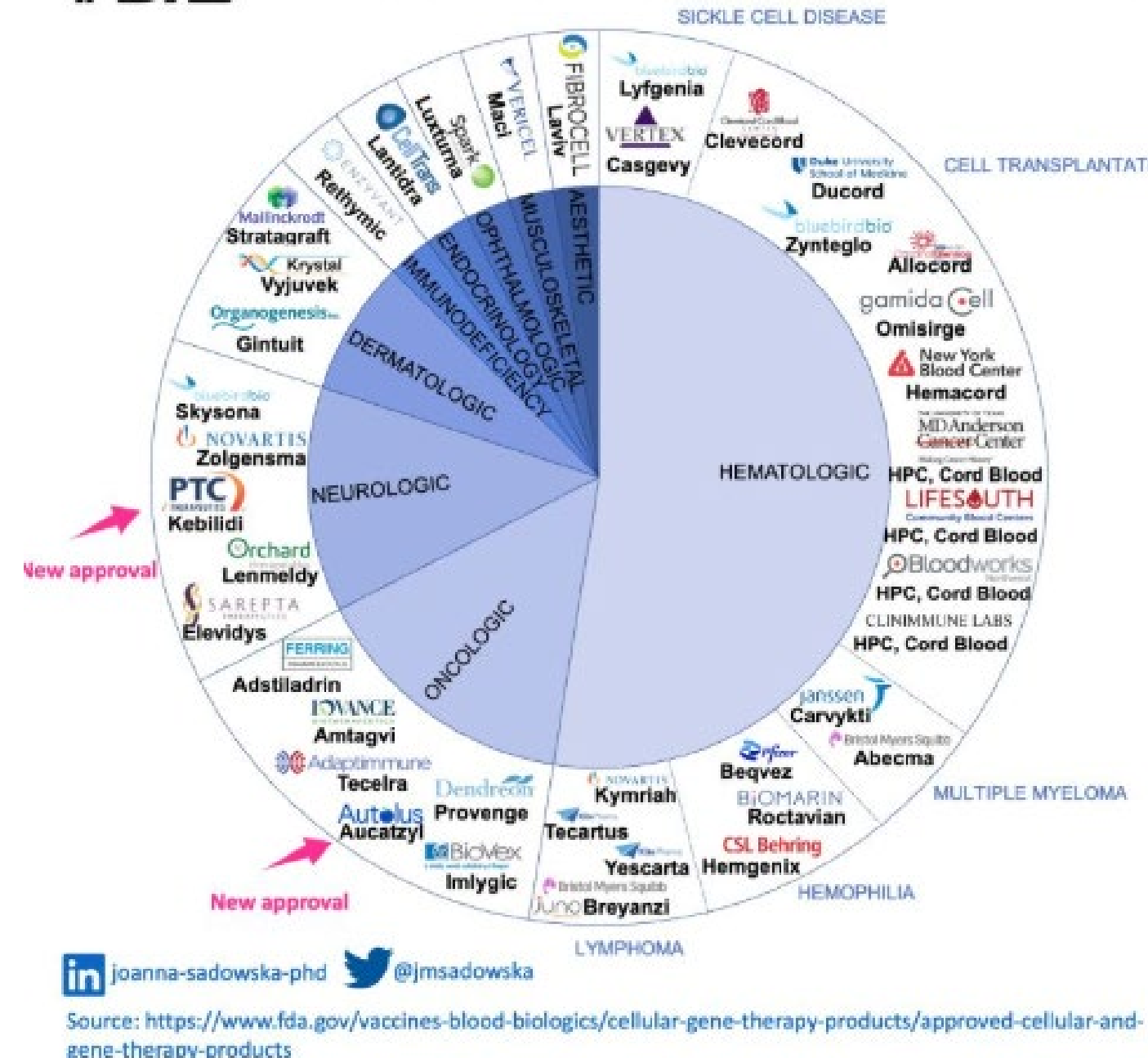


Background

Cellular Therapy (CT)—whether it is chimeric antigen receptor T-cells (CAR-T), tumor infiltrating lymphocyte therapy (TIL) therapy or stem cell transplant—has been used for decades to treat hematological malignancies. More recently, research studies have attempted to treat solid tumors with the same success. Currently, CT is being used increasingly to treat autoimmune, inflammatory and neurologic disorders with the potential to outpace oncology in its applications. In spring 2024, Thomas Jefferson’s Sidney Kimmel Comprehensive Cancer Center (SKCCC) Immune Effector Cellular Therapy (IECT) research team began consulting and collaborating with institutional stakeholders to develop a framework to operationalize its first non-oncology CT trial.

FDA APPROVED CELL AND GENE THERAPIES



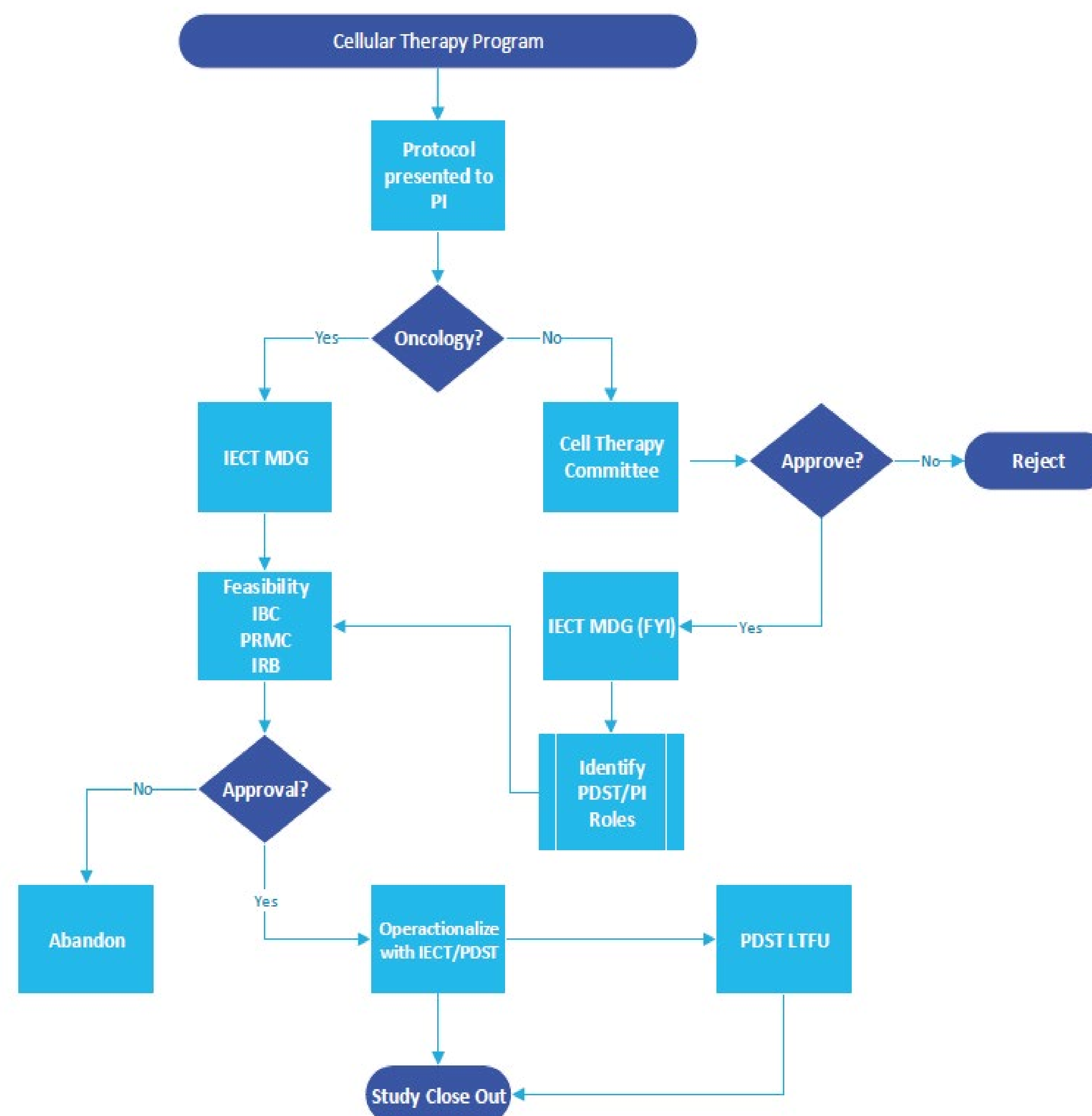
Goals

- Developing the framework would:
- Increase buy-in for investigators
 - Create awareness of CT infrastructure
 - Project and adjust effort
 - Ensure regulatory and research-related costs are covered by Sponsor
 - Align SOPs and systems
 - Delineate roles and responsibilities

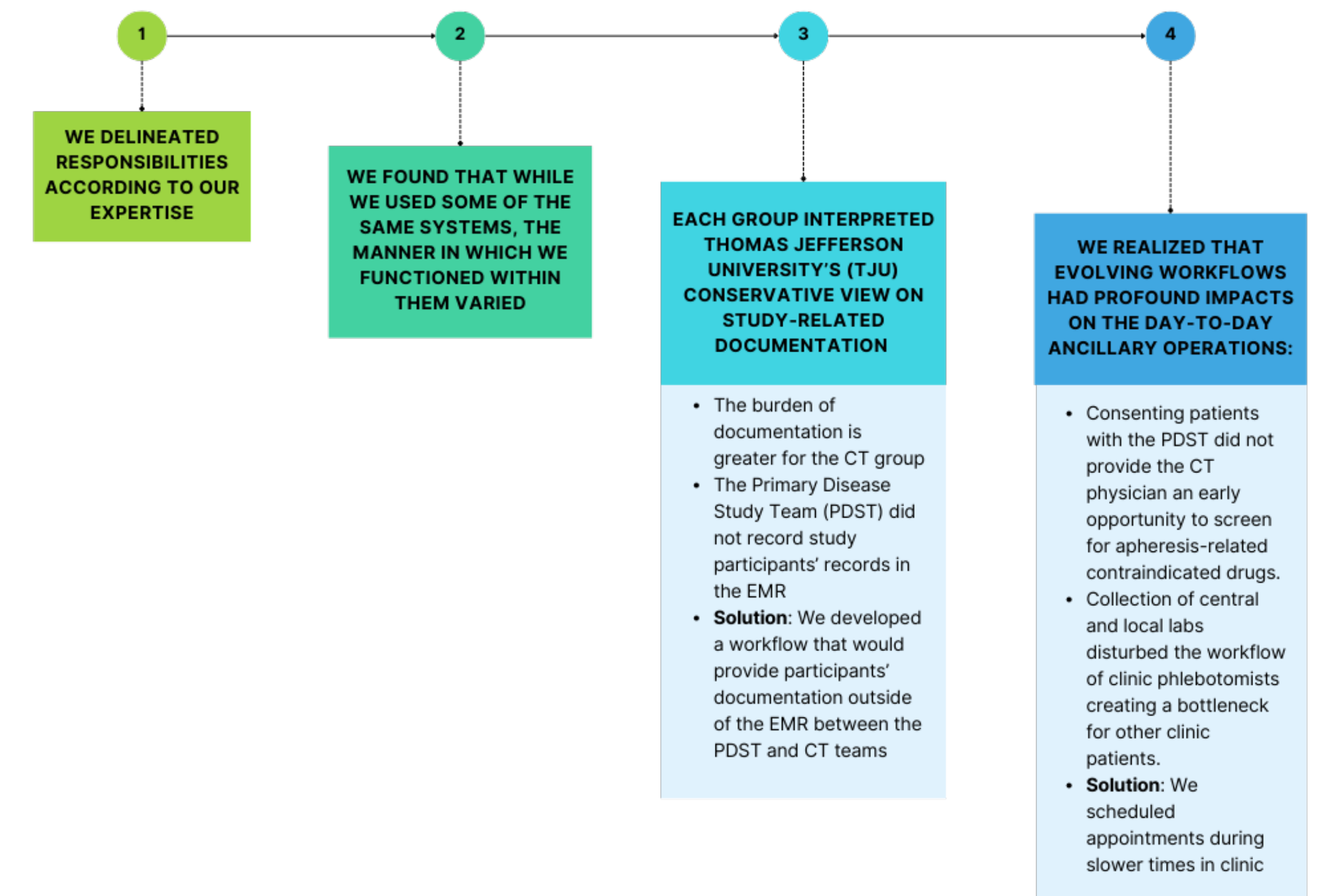
Solutions and Methods

We developed a CT framework through collaborations and consultations with Upper Management, Oncology and Non-Oncology physicians, Budgets and Finance, Regulatory and Research personnel. Our framework is a living document which is updated to reflect lessons learned. Since its creation, it defines PI roles, risks and responsibilities; it outlines study team start-up and protocol-mandated activities; it attempts to align electronic medical records and regulatory systems; it provides financial management and budget development recommendations.

Cellular Therapy Flowchart



Outcomes



Lessons Learned and Future Directions

Operationalizing non-oncology CT is complex and requires coordination between offices across the institution. In order to build this endeavor with the potential to impact so many patients, it is essential that we expand the infrastructure that was initiated in the oncology space. This would include expanding workflows which impact ancillary groups, aligning SOPs across enterprise offices, and centralizing research documentation systems. This expanded operational foundation would serve the program well through its growth.

