

ABSTRACT: 2013 ELAM Institutional Action Project Poster Symposium

Project Title: Pursuing the Future: The Yale Center for Advanced Cell Therapies

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Background: The mission of any academic medical center includes advancement of scientific knowledge and application of this knowledge to improving patient care. Nationwide, there is a gap between important scientific discoveries and their application to clinical care. I am working with the medical school leadership to determine how best to accelerate translation from the bench to clinical trials in cell therapy at the Yale University School of Medicine. Cell and gene therapies have already proven to be effective for some diseases. The proposed "Yale Center for Advanced Cell Therapies (YCACT)" will allow us to adopt the newest therapies and to discover novel treatment modalities.

Purpose: The Purpose of this project is to determine the resources (people, capital, space, infrastructure) needed, and to develop a strategic plan, for launching the "Yale Center for Advanced Cell Therapies."

Approach: During the yearlong ELAM fellowship, I developed a strong network of Key Stakeholders including clinicians, researchers and administrators. To develop a financial plan, I obtained financial data on the income generated for both Yale University and the Yale New Haven Health System for patients admitted during 2012 for allogeneic hematopoietic cell transplantation, one of the key therapeutics that will benefit from enhanced cellular therapies. I identified existing strengths at Yale that will serve as the foundation for the YCACT. In order to develop a strategic plan, I visited and/or spoke with leaders at several academic centers throughout the country that have successful cell therapy programs in order to learn more about their organizational structures, how they were established, the costs of their programs, sources of support, and metrics used to assess value added to their institutions.

Outcomes: Identified existing strengths at Yale including, 1) extensive research strengths in use of cells for therapeutic purposes in the Yale Stem Cell Center, the Yale Cancer Center, as well as the Departments of Immunobiology, Obstetrics and Gynecology, Internal Medicine and Biomedical Engineering; 2) the expertise and motivation of our clinical faculty to translate novel basic science findings to clinical cell therapy protocols, and 3) the recently enhanced clinical trials infrastructure. Working with the leadership and the newly developed coalition of stakeholders, I have determined the best way to proceed to build the YCACT including both building from within (team based science) and recruiting expertise from outside, for which we have established a list of potential recruits. Based on the financial data obtained, I determined the average net collections for each allogeneic hematopoietic stem cell transplantation for the Yale University Medical Group and the hospital system, and through public databases identified the increased transplant volume between 2008 and 2011 at academic centers with cutting edge clinical trials in cell therapy.

Future Vision: Within the next year, the YCACT will recruit new faculty to Yale with expertise in investigator initiated clinical trials using cell therapy, and expand the number and breadth of clinical trials at Yale. Within 3 years, we hope to publish and present data from ongoing clinical trials. Ongoing metrics for success will include 1) publications, 2) number of clinical trials and patients accrued, 3) clinical outcomes, 4) income from grants, clinical enterprise, philanthropy, and corporate investment, as well as 5) patents and licenses.

Pursuing the Future: The Yale Center for Advanced Cell Therapies

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Background

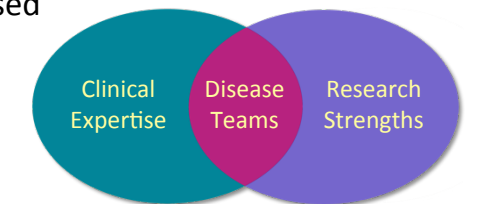
The mission of all academic medical centers includes advancement of scientific knowledge and application of this knowledge to patient care. In response to the necessity that we remedy the national public health problem of translating important scientific findings from the laboratory to clinical care, I am working with the medical school leadership to determine how best to accelerate translation from the bench to clinical trials in cell therapy at Yale University School of Medicine. Cell and gene therapies have been proven to be effective, and may in the future be “standard of care” for some diseases. At Yale, where we desire to both discover novel treatment modalities and adopt the newest therapies discovered elsewhere, I propose to create the Yale Center for Advanced Cell Therapies (YCACT), a highly innovative and effective Center that is actively performing clinical trials, in order to accelerate translation of discoveries from the bench to clinical care.

Approach

- Met with Key Stakeholders individually and as a group
- Worked with professionals in the financial management of the Yale New Haven Medical System (YNHH) and the Yale School of Medicine (YSM).
- Analyzed financial data on income generated from allogeneic hematopoietic stem cell transplantation, a key therapy that will benefit from enhanced cell therapies
- Identified “found pilots” at Yale, including:
 - Extensive research strengths in use of cells for therapeutic purposes (e.g., Yale Stem Cell Center, Yale Cancer Center, Department of Immunobiology)
 - Expertise and motivation of clinical faculty to perform clinical cell therapy trials
 - Enhanced clinical trials infrastructure.
- Visited and/or spoke with leaders at academic centers throughout the country with cell therapy programs
 - Wake-Forest Institute for Regenerative Medicine
 - University of Pittsburgh Medical Center
 - University of California, Davis
 - University of Pennsylvania
 - Johns Hopkins School of Medicine
 - University of Minnesota
- Developed a strategic plan

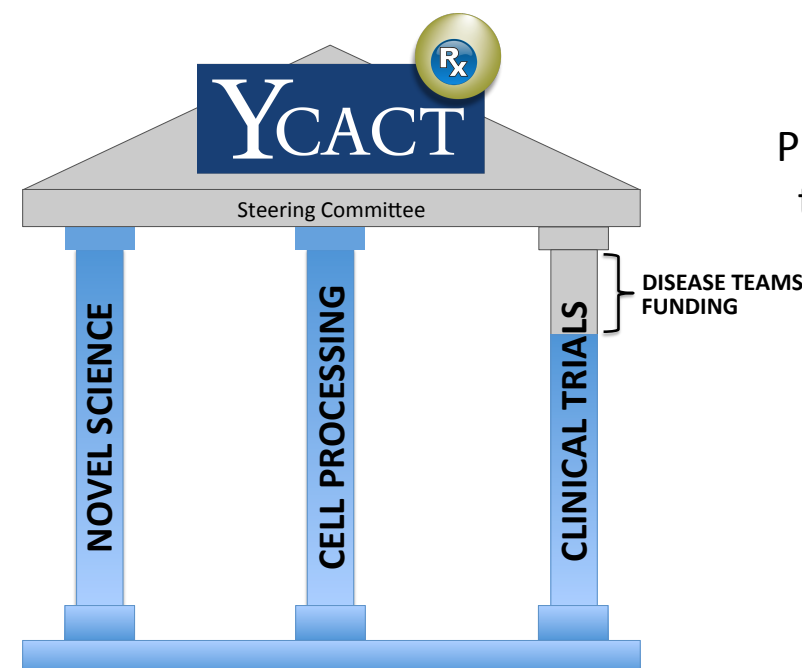
Outcomes and Evaluation

1. Built a network of stakeholders
 - Clinicians
 - Researchers
 - Administration
2. Completed Cost/Benefit analysis for allogeneic transplant program (for both YSM and YNHH)
3. Determined strategy for proceeding: dual approach
 - Build from within (team based science/disease teams)
 - Recruit expertise from outside for which we have established list of potential recruits.
4. Established Metrics for Success
 - Publications and Presentations (national and international)
 - Income (grants, clinical enterprise, philanthropy, corporate investment)
 - Clinical trials (number of trials and number of patients accrued)
 - Clinical outcomes
 - Patents and licenses



Purpose and Objectives

The Purpose of this project was to determine what resources (people, capital, space) would be needed to launch the Yale Center for Advanced Cell Therapies. More specifically, Yale University has not had the resources to fully support clinical trials in cell therapy including multi-institutional trials sponsored by companies and also investigator initiated trials that grow out of basic research findings by Yale investigators or investigators elsewhere. The objectives were to form a coalition of stakeholders, obtain “buy in” from leaders in the Yale medical system as well as the Yale School of Medicine, and to determine the value added by establishing this program.



Pillars of Strength to establish the Yale Center for Advanced Cell Therapies

Next Steps

- Implement Strategic Plan
 - Expand disease teams
 - Recruit new faculty
 - Enhance fundraising activities
 - Establish Steering Committee

