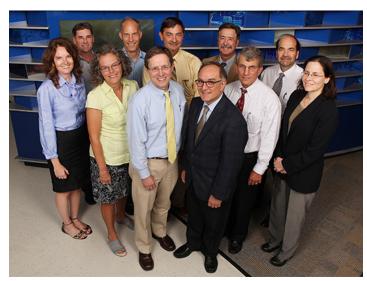


2015 Research Annual Report

Center for Clinical and Translational Science and Training

RESEARCH AND TRAINING DETAILS



Click to view members

Faculty	2
Joint Appointment Faculty	14
Support Personnel	78
Direct Annual Grant Support	\$1,666,875
Peer Reviewed Publications	2
CLINICAL ACTIVITIES AND TRAINING	
Inpatient Encounters	191
Outpatient Encounters	13,178

Research Highlights

CCTST Support Contributes to FDA Approval of Two Drugs for Rare Diseases

Two rare diseases now have FDA-approved treatments, thanks in part to research support provided by the Center for

Clinical and Translational Science and Training (CCTST). Lymphangioleiomyomatosis (LAM) is a rare (5 per million) and frequently fatal lung disease of women, characterized by smooth muscle infiltration and cystic destruction of the pulmonary parenchyma. The safety and efficacy of sirolimus (Rapamune) in the treatment of LAM was established by the multi-site MILES study, led by UC's Frank McCormack, MD. Locally, the trial was based in the CCTST's Clinical Translational Research Center (CTRC), in collaboration with the Rare Lung Disease Consortium led by Cincinnati Children's Bruce Trapnell, MD. FDA approval was announced May 28, 2015.

An arduous twenty-five year process led to the March 17, 2015 FDA approval of Cholbam (cholic acid) for treatment of bile acid synthesis disorders due to single enzyme defects, conditions estimated to occur once in every 80,000 births. Led by Cincinnati Children's faculty James Heubi, MD and Kenneth Setchell, PhD, clinical trials to establish the safety and efficacy of cholic acid therapy were based exclusively in the CCTST's CTRC and its predecessor, the General Clinical Research Center (GCRC). Thanks to this rare example of successful investigator-initiated "bench to bedside" drug development, from conceptualization of the potential therapy to the demonstration of safety and efficacy, a daily pill has replaced liver transplant as treatment for these conditions.

Significant Publications

All publications resulting from projects utilizing CCTST services or the Clinical Translational Research Center (CTRC) are listed in the other divisions' sections of this annual report. A complete listing of these publications is available in the CCTST bibliography.

Division Publications

- 1. Knapke JM, Haynes EN, Kuhnell P, Tsevat J. **NIH** grant awards as a metric of clinical and translational research training effectiveness. *Clin Transl Sci.* 2015; 8:52-6.
- 2. Oster RA, Lindsell CJ, Welty LJ, Mazumdar M, Thurston SW, Rahbar MH, Carter RE, Pollock BH, Cucchiara AJ, Kopras EJ, Jovanovic BD, Enders FT. Assessing statistical competencies in clinical and translational science education: one size does not fit all. Clin Transl Sci. 2015; 8:32-42.

Faculty, Staff, and Trainees

Faculty Members

James E. Heubi, MD, Professor

Leadership Co-Director, Associate Chair, Clinical Research; Associate Dean, Clinical Research; Program Director, CTRC

Joel Tsevat, MD, PhD, Professor

Leadership Co-Director, Associate Dean for Clinical and Translational Research, UC College of Medicine

Joint Appointment Faculty Members

Lara Danziger-Isakov, MD, MPH, Associate Professor (Infectious Diseases)
Research Interests Research Subject Advocate

Thomas DeWitt, MD, Professor (General & Community Pediatrics)

Research Interests Research Education Co-Director

Jacqueline Grupp-Phalen, MD, MPH, Assistant Professor (Emergency Medicine)

Research Interests K12 Training Program Co-Director

John Hutton, PhD, Professor (Biomedical Informatics)

Research Interests Informatics Director

Heidi Kalkwarf, PhD, Professor (General & Community Pediatrics)

Research Interests CTRC Bionutrition Core Director

Maurizio Macaluso, MD, DPH, Professor (Biostatistics & Epidemiology)

Research Interests Biostatistics Director

Frank McCormack, Jr., MD, Professor (Int. Med.-Pulmonary Medicine)

Research Interests Pilot Funding Co-Director

Monica Mitchell, PhD, Professor (Behavioral Medicine & Clinical Psychology)

Research Interests Community Engagement Director

Mark Mitsnefes, MD, Professor (Nephrology)

Research Interests CTRC Director

Scott Powers, PhD, Professor (Behavioral Medicine & Clinical Psychology)

Research Interests CTRC Behavioral Core Co-Director

Marc Rothenberg, MD, PhD, Professor (Allergy & Immunology)

Research Interests K12 Training Program Co-Director

Lori Stark, PhD, Professor (Behavioral Medicine & Clinical Psychology)

Research Interests CTRC Behavioral Core Co-Director

Bruce Trapnell, MD, Professor (Pulmonary Medicine)

Research Interests Pilot Funding Co-Director

Peter White, PhD, Professor (Biomedical Informatics)

Research Interests Informatics Director

Grants, Contracts, and Industry Agreements

Grant and Contract Awards Annual Direct

Heubi, J

Cincinnati Center for Clinical and Translational Sciences and Training

National Institutes of Health (University of Cincinnati)

UL1 TR 001425 6/01/2015-3/31/2019 \$1,315,299

Heubi, J Administration Core \$103,727

White, P/Mitchell M Translational Science Base \$379,132

National I	nstitutes of Health (University of	Cincinnati)			
J/Muglia, L Modules Cincinnati Center for Clinical and Translational Sciences and Training					
	Clancy JP/Grupp-Phalen	Participation Network Resources/Optional	\$142,185		
	Mitsnefes, M/Trapnell B	Research Implementation &	\$509,302		
	Macaluso, M	Research Expertise & Methods	\$180,953		