

Translational Science Interagency Fellowship (TSIF)

The TSIF program is jointly sponsored by NCATS and the FDA and aims to provide training in both translational science and regulatory science. The common goal of NCATS and the FDA is to bring safe and effective drugs, regimens, and devices from the bench to the bedside as quickly and efficiently as possible. To that end, fellows will be trained in preclinical translational science, technology development, and regulatory research and review.

By combining training in translational science and research-related regulatory review, this program will enable fellows to build awareness of regulatory requirements into the early stages of medical product development, improving efficiencies in both the development and review processes. Fellows in this program will develop skills of value to future careers in academia, the pharmaceutical industry, and government.

Eligibility Requirement

This is a three-year program, which accepts up to two new fellows per year. Applicant must:

- Have a Ph.D., M.D., or other doctoral degree in a related discipline or have documentation that all degree requirements will be completed before the start of the fellowship. Assurance to this effect must be supplied in writing by the chair of the dissertation committee (e.g., Ph.D. candidates) or the dean of the school (e.g., M.D. candidates).
- Be a citizen or permanent resident of the United States at the time of application
- Have no more than two years of prior postdoctoral training before joining this fellowship program
- Must be able to pass a Federal background check using Standard Form-85 (read SF-85). Section 14 of the form asks, "In the last year, have you used, possessed, supplied, or manufactured illegal drugs?" The question pertains to the illegal use of drugs or controlled substances in accordance with Federal laws, even though permissible under state laws. Applicants will be required to complete a conflict of interest assessment.

*Selection of fellows will be dependent upon the availability of funds.

Curricula and Responsibilities

Participants will be expected to spend three years in combined training at the FDA and NCATS. It is expected most fellows will spend the first 12 – 18 months of the fellowship at the FDA and the remainder of the fellowship at NCATS. The exact timing of this transition will be project and fellow dependent.

At the FDA, fellows will receive formal training and mentoring in:

- Relevant federal statutes, and
- Regulations, principals, and practices of FDA medical product review

At NCATS, fellows will receive formal training and mentoring in:

- The early stages of technology development, and
- Preclinical and clinical translational science

Descriptions of Projects and Mentors

Review list of mentors and projects here: <https://ncats.nih.gov/training-education/training/TSIF/TSIF-projects-and-mentors>.

Additional Program Details:

- (A) Every effort will be made to match fellows with their first choice of mentors.
- (B) Mentors will provide training in preclinical translational science, clinical trial design/methodology, epidemiology, medical product development, and review of regulatory files. Mentors will also train fellows in ongoing research projects and supervise all regulatory and research activities. Mentors will encourage fellows to participate in the regulatory courses offered by various FDA Centers. Mentors will also discuss relevant scientific conferences and meetings and support fellows training and travel.
- (C) All fellows will participate in the regulatory process at FDA and will be subject to all FDA conflict of interest/ethics rules. The fellows at FDA must complete required FDA financial disclosure forms, abide by FDA non-disclosure and confidentiality rules, and attend FDA staff orientation.
- (D) All fellows will participate in scientific and professional development activities sponsored by the NCATS Intramural Research Program when on-site at NCATS facilities.

How to Apply

Applications are due January 15, 2021 for an earliest start date of September 2021.

Please submit:

- *Curriculum vitae*
- Personal statement of research goals and how these relate to the fields of translational and regulatory science Include in this statement how these goals are aligned with one or more of the project descriptions listed.
- Three letters of reference
- Academic transcript for terminal degree

For more detailed information and application guidelines view the Translational Science Interagency Fellowship (TSIF) Guidelines for Application (PDF)

Send application materials to:

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Chief, Education Branch
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Burden Statement

OMB# 0925-0761
Expiration Date: 07/31/2022

Collection of this information is authorized by The Public Health Service Act, Section 479 (42 USC 287). The information collected in this application will be used to facilitate the acceptance and onboarding of applicants. Rights of participants are protected by The Privacy Act of 1974. The information you provide will be included in a Privacy Act system of records, and will be used and may be disclosed for the purposes and routine uses described and published in the following System of Records Notice (SORN): 09-25-0014 – Clinical Research: Student Records, HHS/NIH/OD/OIR/OE. Participation is voluntary, and there are no penalties for not participating or withdrawing at any time. The information collected will be kept private to the extent provided by law. Names and other identifiers will not appear in any report. Information provided will be combined for all participants and reported as summaries.

Public reporting burden for this collection of information is estimated to average 60 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0761). Do not return the completed form to this address.

Translational Science Interagency Fellowship Projects and Mentors

Running Title of Project:

Translational research in developing predictive toxicology for antisense oligonucleotides (ASOs).

Translational Science Priority Area:

Predictive safety-toxicology for antisense oligonucleotides (ASOs)

FDA Mentor Names:

Lois Freed, Ph.D. and James Wild, Ph.D.

Position and Organizational Affiliation:

Lois Freed: Supervisory Pharmacologist, Division of Neurology 1/2,
Acting Director, Division of Pharmacology/Toxicology,
Office of Neuroscience, CDER, FDA

James Wild: Pharmacologist, Division of Anti-Infectives, CDER, FDA

Contact Information (email/phone):

Lois Freed: Lois.Freed@fda.hhs.gov/ 301-796-1070

James Wild: James.Wild@fda.hhs.gov/ 301-796-4175

NCATS NIH Mentor Names:

Donald C. Lo, Ph.D. and Bryan Trainor, M.D., Ph.D.

Position and Organizational Affiliation:

Donald Lo: Director, Therapeutic Development Branch (TDB)
Division of Preclinical Innovation, NCATS, NIH

Bryan Traynor: Senior Investigator, Chief, Neuromuscular Diseases Research Section
National Institute on Aging (NIA), NIH. On detail to TDB, NCATS, NIH

Contact Information (email/phone):

Donald.lo@nih.gov/ 240-274-0354

traynorb@mail.nih.gov 301-451-7295

Research Project Summary:

Antisense oligonucleotides (ASOs) represent a promising area of therapeutics development for rare monogenic disorders. There are now several approved ASO therapies for rare diseases with many more in development. ASOs can be synthesized to target mRNA in a broad array of genetic diseases, and given this therapeutic targeting flexibility, may be particularly useful as therapeutics for individual or small groups of patients with rare or unique mutations. However, currently traditional animal toxicology testing is required prior to human administration, which is cost prohibitive for single-patient or small patient-group clinical development.

Proposed Project for TSIF fellow:

Fellow will explore translational research approaches to improve predictive toxicology for ASOs, which may include use of iPSC cell culture and electrophysiological methods, microphysiological systems (“tissue chips”), computational modeling, 3D-tissue printing models, and other *in vitro* and *in vivo* test systems to enhance understanding of safety and toxicity of different ASO sequences. Fellow will receive instruction in current procedures for FDA review of ASO nonclinical studies and information on potential gaps in the understanding of ASO-induced toxicities in animals which can adversely impact clinical development. Fellow will assist with development of approaches to nonclinical testing for ASOs in rare genetic diseases and communicate knowledge gained. In a complementary effort, Fellow will compile data from FDA reviews of IND and NDA submissions for ASOs as part of the ongoing development of an established FDA oligonucleotide database and assist with meta-analysis of the data to assess patterns of ASO toxicity.

Relevant Publications:

1. Kim J, Hu C, Moufawad El Achkar C, et al. Patient-Customized Oligonucleotide Therapy for a Rare Genetic Disease. *N Engl J Med.* 2019;381(17):1644-1652.
 2. Mustonen EK, Palomaki T, Pasanen M. Oligonucleotide-based pharmaceuticals: Non-clinical and clinical safety signals and non-clinical testing strategies. *Regul Toxicol Pharmacol.* 2017;90:328-341.
 3. Chi X, Gatti P, Papoian T. Safety of antisense oligonucleotide and siRNA-based therapeutics. *Drug Discov Today.*2017;22(5):823-833
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Running Title of Project:

Unapproved medicines: Identifying US marketed products that pose a public health risk

Translational Science Priority Area:

Data Science – Regulatory Science

FDA Mentor Name:

Tyler Peryea

Position and Organizational Affiliation:

Office of the Commissioner – Office of Health Informatics

Contact Information (email/phone):

tyler.peryea@fda.hhs.gov; 315-775-8953

NCATS Mentor Name:

Noel Southall

Position and Organizational Affiliation:

Pre-Clinical Innovation, Informatics Research Scientist

Contact Information (email/phone):

southalln@mail.nih.gov; 301-480-9836

Research Project Summary:

The Global Substance Registration System (GSRS) is a tool developed jointly by FDA and NCATS which FDA uses to track ingredients in regulated products. GSRS provides unique identifiers (UNII codes) for all ingredients in medicinal products, which sponsors use in their medicinal product descriptions that they

submit to the agency in Structured Product Labelling (SPL) format. Having established this data standard, FDA is now using it to answer questions concerning pharmacovigilance, comparative efficacy, supply chain monitoring, drug repurposing and many other important areas of both basic research and regulatory science. By integrating GSRS UNIs with each FDA Centers' regulatory informatics systems, we can reconstruct the full regulatory history of marketed product ingredients.

Proposed Project for TSIF fellow:

Commercial transactions of drugs in the US require a National Drug Code (NDC), and updated regulations coming into effect for this program in 2020 require ALL product sponsors to register their products with FDA in the SPL standard using UNIs to list product ingredients. By comparing listed ingredients against Centers' regulatory history for those ingredients, the fellow will be able to identify, *for the first time*, the scope of unapproved products in the marketplace. Understanding gaps in regulatory process and vulnerabilities in the current regulatory regime will help us make products safer for consumers. Initial reports from some hospital systems imply that as many as 40% of the unique NDCs in hospital records have no corresponding SPL record. The fellow would work to establish better reports to understand the nature of the missing NDCs, estimate the impact that incomplete NDC data has on FDA and NCATS goals, discover and process existing unconnected datasets to mitigate issues, and propose and implement some data strategies to help fill in the gaps in the NDC data to better leverage the power of GSRS, SPL and the various EHR systems toward improving human health as per HHS mandates.

Relevant Publications:

1. ACS Pharmacol Transl Sci. 2019 Aug 20;2(6):497-500. Freedom of Information Act Access to an Investigational New Drug Application. Noel T Southall
 2. *Invited article under review* - Nuc Acids Res. Global Substance Registration System: Consistent scientific descriptions for substances related to health. Tyler Peryea, Noel Southall, et al.
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Running Title of Project:

Regulatory Science Challenge for Computational Prediction of Safety Pharmacology

Translational Science Priority Area:

Predictive safety modeling

FDA Mentor Name:

Rebecca Racz, PharmD

Position and Organizational Affiliation:

Pharmacologist, Division of Applied Regulatory Science, Office of Clinical Pharmacology, Office of Translational Sciences, Center for Drug Evaluation and Research, FDA

Contact Information (email/phone):

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NCATS Mentor Name:

Noel Southall, PhD

Position and Organizational Affiliation:

Informatics, Division of Preclinical Innovation, NCATS

Contact Information (email/phone):

southalln@mail.nih.gov; 301-480-9836

Research Project Summary:

While companies provide in vitro testing to screen potential secondary targets, it is not plausible to screen all targets that could affect drug safety or lead to adverse events. Computational algorithms that can accurately identify targets of potential concern would be beneficial in anticipating clinical safety risks and understanding adverse events seen during development. Unfortunately, the community has not been able to establish whether current prediction tools are fit for this purpose. FDA houses secondary pharmacology in vitro screening data from a large number of drugs that could be used to independently test computational algorithms within FDA.

Proposed Project for TSIF fellow:

Fellow will design a community challenge to test the predictive performance of available algorithms and publish the results. In vitro data at FDA will be used to evaluate the predictive performance of submitted algorithms. Fellow would begin work by conducting a survey and evaluation of current algorithms and tools using published data and then work with mentors to enable the submission of algorithms to FDA to be tested on data from the FDA secondary pharmacology database.

Relevant Publications:

1. Predicting potential adverse events using safety data from marketed drugs. Daluwatte C, Schotland P, Strauss DG, Burkhart KK, **Racz R**. *BMC Bioinformatics*. 2020 Apr 29;21(1):163. doi: 10.1186/s12859-020-3509-7.
2. Evaluating kratom alkaloids using PHASE. Ellis CR, **Racz R**, Kruhlak NL, Kim MT, Zakharov AV, **Southall N**, Hawkins EG, Burkhart K, Strauss DG, Stavitskaya L. *PLoS One*. 2020 Mar 3;15(3):e0229646. doi: 10.1371/journal.pone.0229646.
3. Public Health Assessment via Structural Evaluation of Newly Identified Drugs of Abuse. Ellis CR, **Racz R**, Kruhlak NL, Kim MT, Hawkins EG, Strauss DG, Stavitskaya L. *Clin Pharmacol Ther*. 2019 Jul;106(1):116-122. doi: 10.1002/cpt.1418.

Running Title of Project:

Kidney Organoids for Drug Efficacy, Toxicity and Metabolism Studies

Translational Science Priority Area:

Evidence Generation (Goal 1/ Objective b)

FDA Mentor Name:

Alexandre Ribeiro

Position and Organizational Affiliation:

Staff Fellow, Division of Applied Regulatory Science, Office of Clinical Pharmacology, Office of Translational Sciences, CDER

Contact Information (email/phone):

Alexandre.Ribeiro@fda.hhs.gov; 301-796-0126

NCATS Mentor Name:

Marc Ferrer

Position and Organizational Affiliation:

Director, 3D Tissue Bioprinting Laboratory, Division of Preclinical Innovation, NCATS

Contact Information (email/phone):

ferrerm@mail.nih.gov; 240-515-4118

Research Project Summary:

Kidney organoids derived from induced pluripotent stem cells (iPSCs) and developed by the Freedman lab at the University of Washington are being evaluated at NCATS and CDER as 3D cellular assay platforms for the potential of predicting drug metabolism and drug efficacy/ toxicity. Within their 3D complexity, these cellular systems have been demonstrated to contain regions with cells that represent different features of kidney morphology, cellular complexity, and function, holding great potential for drug development.

Proposed Project for TSIF fellow:

The fellow will work towards the evaluation and characterization of an iPSC-derived kidney organoid platform as a 3D cellular system with enhanced physiology that can be assayed to predict drug metabolism and efficacy/ toxicity in a normal vs Polycystic Kidney Disease (PKD) cellular background. 1) At FDA and NCATS, the fellow will learn the protocols for kidney organoid production in a 96- or 384-well plate format; 2) At FDA, the fellow will test the ability to evaluate drug metabolism with compounds that are known substrates for renal cytochrome P450 (CYP) and UDP-glucuronosyltransferase (UGT) enzymes using liquid chromatography-mass spectrometry assays established at CDER. Research on evaluating drug toxicity that targets the renal interstitium will also be planned for next research phase. 3) At NCATS, the fellow will help develop a cell imaging based assay to establish efficacy effect of compounds on PKD phenotypes and study the toxic effect of compounds on normal and PKD organoids models. In addition to imaging extracellular matrix components for screening drug-induced defects in the renal interstitium, cell viability assays will be performed, like CellTiterGlo, live/ dead fluorescence assays and organoid structure will be analyzed from brightfield images. Altogether, interpretation of toxicity and efficacy results as predictive of clinical effects will take into consideration information on drug metabolism.

Relevant Publications:

1. Cruz, NM et al. Organoid cystogenesis reveals a critical role of microenvironment in human polycystic kidney disease; Nat Mater. 2017 Nov;16(11):1112-1119. doi: 10.1038/nmat4994
 2. Czerniecki, SM et al. High-throughput screening enhances kidney organoid differentiation from human pluripotent stem cells and enables automated multidimensional phenotyping; Cell Stem Cell. 2018 Jun 1;22(6):929-940.e4. doi: 10.1016/j.stem.2018.04.022.
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Running Title of Project:

Characterizing Regulatory and Product Development Challenges for “N=1” Oligonucleotide programs using computational and clinical pharmacology approaches.

Translational-Regulatory Science Priority Area:

Knowledge management framework for antisense oligonucleotides (ASOs) in rare diseases

FDA Mentor Name:

Hobart Rogers Pharm.D., Ph.D.

Position and Organizational Affiliation:

Clinical Pharmacologist, FDA/CDER/OTS/OCP/DTPM

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NCATS Mentor Names:

Donald C. Lo, Ph.D., Bryan Traynor, M.D., Ph.D., and Ewy Mathé, Ph.D.

Position and Organizational Affiliation:

Donald Lo: Director, Therapeutic Development Branch (TDB)
Division of Preclinical Innovation, NCATS

Bryan Traynor: Senior Investigator, Chief, Neuromuscular Diseases Research Section
National Institute on Aging (NIA). On detail to TDB, NCATS

Ewy Mathé: Director of Informatics
Division of Preclinical Innovation, NCATS

Contact Information (email/phone):

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ewy.mathe@nih.gov/ 301.402.8953

Research Project Summary:

Antisense oligonucleotides (ASOs) represent a new class of therapeutics aimed at augmenting RNA in ways previously inaccessible to small molecules and therapeutic biologics. Moreover, ASOs are considered a “platform” technology whereby a customized oligonucleotide can be developed using similar starting materials combined with an understanding of molecular genetics and bioinformatics. This platform allows for the development of “N=1” customized oligonucleotides with the intent to treat rare genetic diseases unique to individuals or small numbers of patients previously not commercially viable for pharmaceutical companies. The goal of this project is to better ascertain the types of translational science and regulatory challenges posed by the “N=1” oligonucleotide programs and address any gaps where regulatory guidance and other assessments, such as computational approaches may need to be developed.

Proposed Project for TSFI fellow:

The Fellow will create a knowledge management framework for “N=1” oligonucleotide programs to support regulatory decision-making across therapeutic areas. This Fellow will then systematically review information from this database to identify opportunities to improve guidance to sponsors/investigators, and gaps in policies related to the regulatory oversight of these programs. The Fellow will also evaluate dosing, efficacy, and safety issues of the database to identify opportunities to communicate to stakeholders to better refine development. Where possible, the Fellow will evaluate the utility of biomarkers in assessing the PD, and efficacy of each of these “N=1” oligonucleotide programs. These findings may help inform future dosing and dosing regimens of other ASO programs.

Relevant Publications:

1. Pacanowski MA. Translating Precision. Clin Transl Sci. 2017;10(2):56-7.
2. Madabushi R, Benjamin JM, Grewal R, et al. The US Food and Drug Administration’s Model-informed Drug Development Paired Meeting Pilot Program: Early Experience and Impact. Clin Pharmacol Ther. 2019;106(1):74-8.

3. Hagedorn PJ, Yakimov V, Ottosen S, et al Hepatotoxic potential of therapeutic oligonucleotides can be predicted from their sequence and modification pattern. *Nucleic Acid Therapeutics*. 2013;23(5):302-10.
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Running Title of Project:

Repurposing for Neglected Infectious Diseases: Project Lifecycle from Bench to Translational to Regulatory Science

Translational Science Priority Area:

Regulatory Science of Repurposing

FDA Mentor Name:

Heather Stone, MPH; Leonard Sacks, MD

Position and Organizational Affiliation:

Heather Stone, MPH: Health Science Policy Analyst, CDER/OMP/IO/CM

Leonard Sacks, MD.: Associate Director for Clinical Methodologies, CDER/OMP/IO/CM

Contact Information (email/phone):

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Leonard Sacks, MD.: leonard.sacks@fda.hhs.gov

NCATS Mentor Name:

Noel Southall, PhD

Position and Organizational Affiliation: Informatics/DPI/NCATS

Contact Information (email/phone): southalln@mail.nih.gov; 415-279-2759

Research Project Summary:

Drug repurposing spans a continuum of approaches ranging from in silico modeling and high throughput screening to clinical trials that support regulatory approval. For future researchers to understand the opportunities and challenges involved in drug repurposing, they must be exposed to the full breadth of this continuum. This will give them unique insights into the challenges and potential solutions for the roadblocks that are often found with repurposing.

Proposed Project for TSIF fellow:

Fellows would spend the first 1.5 years at NCATS learning about the process of pre-clinical drug development and identification of potential new uses of existing drugs. They would learn about the challenges of drug discovery from both the bench and the informatics perspectives by participating as a research member on a screening project team. They would then transition to the second half at FDA where they would focus on the clinical and regulatory aspects of drug repurposing. Fellows would gain experience on the level of evidence and types of trials necessary to support the regulatory approval of a supplementary indication. An important outcome would be a review article outlining the regulatory challenges of drug repurposing, and potential nonclinical, clinical and regulatory solutions. Training of investigators/ clinicians on drug repurposing is an important but neglected area that addresses gaps in drug development strategies for areas of unmet medical need.

Relevant Publications:

1. "CURE ID App Lets Clinicians Report Novel Uses of Existing Drugs"
<https://www.fda.gov/drugs/science-and-research-drugs/cure-id-app-lets-clinicians-report-novel-uses-existing-drugs>.
 2. A cell-based, infectious-free, platform to identify inhibitors of lassa virus ribonucleoprotein (vRNP) activity. Cubitt B, Ortiz-Riano E, Cheng BY, Kim YJ, Yeh CD, Chen CZ, Southall NOE, Zheng W, Martinez-Sobrido L, de la Torre JC. *Antiviral Res.* **2020** Jan;173:104667.
 3. The use or generation of biomedical data and existing medicines to discover and establish new treatments for patients with rare diseases - recommendations of the IRDiRC Data Mining and Repurposing Task Force. Southall NT, et al. *Orphanet J Rare Dis.* **2019** Oct 15;14(1):225.
 4. The NCATS Pharmaceutical Collection: a 10-year update. Huang R, Zhu H, Shinn P, Ngan D, Ye L, Thakur A, Grewal G, Zhao T, Southall N, Hall MD, Simeonov A, Austin CP. *Drug Discov Today.* **2019** Dec;24(12):2341-2349.
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Running Title of Project:

A microphysiological skin model of atopic dermatitis for screening immunomodulatory mesenchymal stromal cell therapies

Translational Science Priority Area:

Microphysiological systems, Platforms for cell-based therapies

FDA Mentor Name:

Kyung Sung

Position and Organizational Affiliation:

Principal Investigator, CBER/OTAT/DCGT/CTTB

Contact Information (email/phone):

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NCATS Mentor Name:

Marc Ferrer

Position and Organizational Affiliation:

Director, 3-D Tissue Bioprinting Laboratory, NIH

Contact Information (email/phone):

marc.ferrer@nih.gov, 301-480-9845

Research Project Summary:

Atopic dermatitis (AD) is a chronic, relapsing inflammatory skin disease that affects about 20% of children worldwide and has no cure. The development of 3D in vitro models that recapitulate the pathophysiology of AD would provide new ways to evaluate and screen for therapies. We propose to develop a 3D microphysiological skin model of AD for evaluating cell-based products, in particular

mesenchymal stromal cells (MSCs). AD is in part believed to be driven by overactivated T-cells that take on a Th2 phenotype [1]. We will miniaturize the 3D-printed model of AD, which consists of keratinocytes, iPSC-derived endothelial cells, pericytes, and fibroblasts cultured in a fibrin/PLGA matrix [2], and will include activated Th2 CD4⁺ T- cells that secrete Th2 cytokines. We will then test how application of MSCs of varying donor origin and passage number to the model can suppress the activation of the Th2 T-cells and inhibit the generation of AD-disease like phenotype in the model. This will test one of the main mechanisms by which MSCs are believed to treat atopic dermatitis in pre-clinical and clinical models [3].

Proposed Project for TSIF fellow:

We propose that the fellow will spend the first 1.5 year of the project in the Ferrer lab at the NCATS developing a microphysiological AD model. The current AD model in the Ferrer lab involves applying IL-4, a cytokine secreted by Th2 T-cells, to induce an AD phenotype in the skin model. The fellow will evaluate how applying activated Th2 T-cells to the model can recapitulate the effects that IL-4 has on inducing an AD phenotype. In the second 1.5 year of the project, the fellow will work in the Sung lab at the FDA/CBER to test how application of MSCs from varying donors and passage to the model can be used to suppress the Th2 T-cells and treat AD in the model. This will test how MSC functional heterogeneity influences the ability of these cells to treat this disease.

Relevant Publications:

1. E.B. Brandt, U. Sivaprasad, Th2 cytokines and atopic dermatitis, *Journal of clinical & cellular immunology* 2(3) (2011).
2. X. Liu, S. Michael, K. Bharti, M. Ferrer, M.J. Song, A biofabricated vascularized skin model of atopic dermatitis for preclinical studies, *Biofabrication* 12(3) (2020) 035002.
3. S.R.T. Daltro, C.S. Meira, I.P. Santos, R. Ribeiro dos Santos, M.B.P. Soares, Mesenchymal Stem Cells and Atopic Dermatitis: A Review, *Frontiers in Cell and Developmental Biology* 8 (2020) 326.