



## 58 UCSF-Stanford CERSI Collaborative Research Projects with the FDA

<https://pharm.ucsf.edu/cersi/research>

Project Name	FDA Center	PI Name
<b>Patient Preference and Patient Reported Outcomes</b>		
The Impact of Race and Ethnicity on Responses to Heart Failure PROM *	CDRH	Courtney Lyles (UCSF) Urmimala Sarkar (UCSF)
Patient Preferences: Upper Limb Prostheses	CDRH	Leslie Wilson (UCSF)
PROs for Minimally Invasive Glaucoma Surgery	CDRH	Kuldev Singh (Stanford)
Pediatric Patient Preferences *	CDRH	Korey Hood (Stanford)
Characterizing Risk-Benefit Tradeoff in Opioid-based Chronic Pain Treatment	CDRH	Sean Mackey (Stanford)
PROM for Pediatric Heart Failure	CDRH	Christopher Almond (Stanford)
Assessment of Patient Tolerance for Risk Associated with High Intensity Focused Ultrasound (HIFU) for the Ablation of Prostate Tissue	CDRH	Geoffrey Sonn (Stanford)
<b>Generic Drugs</b>		
Effects of Excipients in Generic Drugs on Intestinal Drug Transporters *	CDER	Kathy Giacomini (UCSF)
The Effect of Excipients on the Oral Absorption of Fexofenadine in Humans	CDER	Kathy Giacomini (UCSF)
Chemoinformatic Tools to Predict the Effect of Excipients in Generic Drugs *	CDER	Brian Shoichet (UCSF)
<b>Precision Medicine</b>		
Role of Ancestry in Genetic Diagnostics	OHI/OCS	Snehit Prabhu (Stanford)
TOBIAS – A Clinical Decision Support Tool to Personalize NGS Diagnostic Test Results Based on Genetic Ancestry	OHI/CDRH/ OMHHE	Snehit Prabhu (Stanford)
HYDRA – A Federated Computational Infrastructure to Enable Inclusive, Large-scale Precision Medicine Studies	OHI/CDRH/ OMHHE	Snehit Prabhu (Stanford)
Causes of Real-life NGS Variability *	OHI/OCS	Dmitri Petrov (Stanford)

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<b>Precision Medicine</b>		
Network Integration for Precision Medicine Drug Models *	CDER	Russ Altman (Stanford)
Precision Medicine Initiative – Education *	OHI/OCS	Russ Altman (Stanford)
Next Generation Text Analytics *	OHI/OCS	Russ Altman (Stanford)
Evaluation of the impact of Genetic Variability on Drug Target Interactions using Structural Bioinformatics *	CDER	Russ Altman (Stanford)
Identifying Genetic Mechanisms of Doxorubicin-Induced Cardiotoxicity	OWH	Joesph Wu (Stanford)
HIV Genomic Surveillance in Cameroon by Next-Generation Sequencing	CBER	Charles Chiu (UCSF)

<b>Pharmacovigilance</b>		
Improving Adverse Event Detection Related to Biologic Immunosuppressant Use – A Pilot Study of the BERT Deep Learning Model Adapted to Real-world Clinical Notes	CDER/CBER	Vivek Rudrapatna (UCSF)
Health Citizen Hospital Pilot *	OHI	Ida Sim (UCSF)
Data Science Methods for Post-marketing Surveillance of AI Diagnostic Tools	CDER	Daniel Rubin (Stanford)
Improving the Efficiency and Rigor of Pharmacovigilance at FDA *	CDER/CBER	Russ Altman (Stanford)
Use of NLP to Analyze Medication Error Reports and Improve FAERS Reports *	CDER	Russ Altman (Stanford)
Improving the Diagnostic Accuracy of ADR Signal Detection *	CDER/CDRH	Nigam Shah (Stanford)

<b>Special Populations</b>		
Predicting Pediatric Dosing for Medical Countermeasures	CDER	Kathy Giacomini (UCSF)
Renal Impairment in New Drug Development *	CDER	Kathy Giacomini (UCSF)
Characterizing Population-Specific Clinical Asthma Profiles	OMHHE	Esteban Burchard (UCSF)
Usability Testing of Virtual Reality for Opioid-Sparing Pain Management Among Diverse Patients	OMHHE	Urmimala Sarkar (UCSF) Courtney Lyles (UCSF)
Safer Labeling of Pediatric Medications	OMHHE	Lee Sanders (Stanford)

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<b>Special Populations</b>		
Comprehensive Assessment of Sex-Differential Smoking-related Effects in Publicly Available Gene Expression Data	OWH	Russ Altman (Stanford)
Creating a Framework for a National Adaptive Platform Trial to Evaluate Pediatric Medical Devices	CDRH	Christopher Almond (Stanford)
Renal Impairment in New Drug Development: Phase II	CDER	Timothy Meyer (Stanford)

<b>Clinical Trials</b>		
OneSource *	CDER	Laura Esserman (UCSF)
OneSource Phase 2	CDER	Laura Esserman (UCSF)
Identification and Validation of Biomarkers for Breast Cancer Resistance Protein (BCRP)	CDER	Kathy Giacomini (UCSF)
Developing an Operational Framework for Defining the Strength of Evidence in Therapeutic Development *	CDER	Steve Goodman (Stanford)

<b>Medical Devices</b>		
Identification of Pacemaker and Implantable Cardioverter-Defibrillator Lead Failure Using Remote Monitoring Data	CDRH	Sanket Dhruva (UCSF)
Safe Algorithmic Change Protocols for Modifications to AI/ML-Based Software as a Medical Device	CDRH	Jean Feng (UCSF)
Spinal Orthopaedic Device Mechanics *	CDRH	Jeffrey Lotz (UCSF)
Advancing Computational Modeling in the Regulatory Evaluation of Spinal Fusion Cages *	CDRH	Jeffrey Lotz (UCSF)
Development of Thrombogenicity Testing Methods for Medical Devices	CDRH	Shuvo Roy (UCSF)
Development and Evaluation of Computational Test Methods Leveraging Real-world and Simulated Datasets for Predictive Medical Device Alarm Algorithms *	CDRH	Xiao Hu (UCSF)

<b>Biologics</b>		
Using the University of California Clinical Data Warehouse to Evaluate the Safety and Efficacy of Biologics, including Blood Transfusions, Vaccines, CAR-T cell Therapies, and other CBER Regulated Products	CBER	Atul Butte (UCSF)

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<b>Biologics</b>		
Isolating Exosomes using a novel ExoTIC device from HIV-infected Patient Plasma and Saliva	CBER	Utkan Demirci (Stanford)
An Unbiased Analysis of Identification and Assessment of Cas9/gRNA Potential Off-Target Sites in Clinical Development of Ex Vivo Manufactured Genome Edited Cell Products	CBER	Matthew Porteus (Stanford)
Development of New and Innovative Methods for Automated Reporting for CBER-Regulated Biological Products	CBER	Tina P-Boussard (Stanford)
Development of New Machine Learning Algorithms to Quantify Treatment Effectiveness and Adverse Outcomes	CBER	James Zou (Stanford)
Tissue Chips for Multipotent Stromal Cell Manufacturing	CBER	Ngan Huang (Stanford)
Methods to Inactivate Pathogens in Blood *	CBER	Eric Kool (Stanford)
Stem Cell Mass Cytometry *	CBER	Sean Bendall (Stanford)

<b>COVID-19</b>		
A Rapid Query Model to Address Prioritized COVID-19 Questions Using EHR Data	Office of the Commissioner	Atul Butte (UCSF)
OneSource Phase III: Demonstration of EHR/eCRF integration in the COVID-19 critical care environment	CDER	Laura Esserman (UCSF)
OneSource: SMART on FHIR for I-SPY COVID-19 Trial	CDER	Laura Esserman (UCSF)

<b>Miscellaneous</b>		
Developing Frameworks and Tools for Integration of Digital Health Tools into Clinical Practice	CDRH	Andrew Auerbach (UCSF)
Multi-organ Microphysiological Systems for Modeling Clinical Drug Effects	CDER	Edward Hsiao (UCSF) Kevin Healy (UC Berkeley)
Gut Microbiome: Knowledge Synthesis *	OHI	Peter Turnbaugh (UCSF)

\* Completed research projects

**FDA Centers and Offices**

- CDER = Center for Drug Evaluation and Research
- CDRH = Center for Devices and Radiological Health
- CBER = Center for Biologics Evaluation and Research
- OMHHE = Office of Minority Health and Health Equity
- OWH = Office of Women's Health
- OHI = Office of Health Informatics
- OCS = Office of the Chief Scientist
- Office of the Commissioner