



## UCSF-Stanford CERSI Collaborative Research Projects

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

Project Name	FDA Centers	Academic PI(s)
<b>Biologics Research Projects</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)
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 Hernandez-Boussard (Stanford)
Improving Adverse Event Detection Related to Biologic Immunosuppressant Use – A Pilot Study of the BERT Deep Learning Model Adapted to Real-world Clinical Notes	CBER	Vivek Rudrapatna (UCSF) Atul Butte (UCSF)
Tissue Chips for Multipotent Stromal Cell Manufacturing	CBER	Ngan Huang (Stanford)
Development of New Machine Learning Algorithms to Quantify Treatment Effectiveness and Adverse Outcomes (COMPLETED)	CBER	James Zou (Stanford)
Methods to Inactivate Pathogens in Blood (COMPLETED)	CBER	Eric Kool (Stanford)
Single Cell Mass Cytometry Based Assessment of MSCs (COMPLETED)	CBER	Sean Bendall (Stanford)
<b>Drug Research Projects</b>		
The Effect of Excipients on the Oral Absorption of Fexofenadine in Humans	CDER	Kathy Giacomini (UCSF)
OneSource Phase 2: Source Data Capture from Electronic Health Records using Standardized Clinical Research Data	CDER	Laura Esserman (UCSF)
Identification and Validation of Biomarkers for Breast Cancer Resistance Protein (BCRP)	CDER	Kathy Giacomini (UCSF)

Multi-organ Microphysiological Systems for Modeling Clinical Drug Effects	CDER	Edward Hsiao (UCSF) Kevin Healy (UC Berkeley)
Effects of Excipients in Generic Drugs on Intestinal Drug Transporters (COMPLETED)	CDER	Kathy Giacomini (UCSF)
Chemoinformatic Tools to Predict the Effect of Excipients in Generic Drugs (COMPLETED)	CDER	Brian Shoichet (UCSF)
OneSource: e-Source Checklist (COMPLETED)	CDER	Laura Esserman (UCSF)
Developing an Operational Framework for Defining the Strength of Evidence in Therapeutic Development (COMPLETED)	CDER	Steve Goodman (Stanford)
Gut Microbiome: Knowledge Synthesis (COMPLETED)	OHI	Peter Turnbaugh (UCSF)
Healthy Citizen Hospital Pilot (COMPLETED)	OHI	Ida Sim (UCSF)
Improving the Efficiency and Rigor of Pharmacovigilance (PV) at FDA (COMPLETED)	CDER/CBER	Russ Altman (Stanford)
Use of natural language processing/machine learning to analyze medication error reports and improve the quality of data submitted to the FDA Adverse Event Reporting System (FAERS) (COMPLETED)	CDER	Russ Altman (Stanford)
Improving the Diagnostic Accuracy of ADR Signal Detection by Combining Signals from Spontaneous Reports and Electronic Health Records (COMPLETED)	CDER/CDRH	Nigam Shah (Stanford)
Data Science Methods for Post-marketing Surveillance of AI Diagnostic Tools and algorithm-based therapeutics (COMPLETED)	CDER	Daniel Rubin (Stanford)

<b>Medical Device Research Projects</b>		
Development of Thrombogenicity Testing Methods for Medical Devices	CDRH	Shuvo Roy (UCSF)
Safe Algorithmic Change Protocols for Modifications to AI/ML-Based Software as a Medical Device	CDRH	Jean Feng (UCSF)
Identification of Pacemaker and Implantable Cardioverter-Defibrillator Lead Failure Using Remote Monitoring Data	CDRH	Sanket Dhruva (UCSF)
The Digital Variome: Understanding the Implications of Digital Tools on Health	CDRH	Andrew Auerbach (UCSF)
Developing Frameworks and Tools for Integration of Digital Health Tools into Clinical Practice	CDRH	Andrew Auerbach (UCSF)
Post-Market Evaluation of Smartwatch Cardiovascular Notifications	CDRH	Mintu Turakhia (Stanford)

Advancing Computational Modeling in the Regulatory Evaluation of Spinal Fusion Cages (COMPLETED)	CDRH	Jeffrey Lotz (UCSF)
Spinal Orthopaedic Device Mechanics (COMPLETED)	CDRH	Jeffrey Lotz (UCSF)
Development and Evaluation of Computational Test Methods Leveraging Real-world and Simulated Datasets for Predictive Medical Device Alarm Algorithms (COMPLETED)	CDRH	Xiao Hu (UCSF)

#### Patient Focused Research Projects

Patient Reported Outcomes for Minimally Invasive Glaucoma Surgery	CDRH	Kuldev Singh (Stanford)
Characterizing Risk-Benefit Tradeoff in Opioid-based Chronic Pain Treatment	CDRH	Sean Mackey (Stanford)
Adapting a Measure of Heart Failure to an Adolescent Population	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)
Development, Implementation, and Evaluation of an Open Source Software Program to Support Patient-based Estimation of Clinically Meaningful Levels and Change Scores for Patient Reported Outcome Measures	CDRH	Sean Mackey (Stanford)
The Impact of Race and Ethnicity on Responses to Heart Failure Patient-Reported Outcome Measures (COMPLETED)	CDRH	Courtney Lyles (UCSF) Urmimala Sarkar (UCSF)
Comparing Qualitative and Quantitative Approaches to Eliciting Patient Preferences: A Case Study on Innovative Upper Limb Prostheses (COMPLETED)	CDRH	Leslie Wilson (UCSF)
Mapping a Better Approach to Obtaining Pediatric Patient Preferences (COMPLETED)	CDRH	Korey Hood (Stanford)

#### Precision Medicine Research Projects

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)
Identifying Genetic Mechanisms of Doxorubicin-Induced Cardiotoxicity	OWH	Joseph Wu (Stanford)
HIV Genomic Surveillance in Cameroon by Next-Generation Sequencing	CBER	Charles Chiu (UCSF)

Assessing the Potential for Patient-Specific and Genome Edited Induced Pluripotent Cell-Based Models to Streamline Clinical Drug Development for Rare Diseases	CDER	Joseph Wu (Stanford)
Role of Ancestry in Genetic Diagnostics (COMPLETED)	OHI/OCS	Snehit Prabhu (Stanford)
Causes of Real-life NGS Variability (COMPLETED)	OHI/OCS	Dmitri Petrov (Stanford)
Network Integration for Precision Medicine Drug Models (COMPLETED)	CDER	Russ Altman (Stanford)
Precision Medicine Initiative – Education (COMPLETED)	OHI/OCS	Russ Altman (Stanford)
Next Generation Text Analytics (COMPLETED)	OHI/OCS	Russ Altman (Stanford)
Evaluation of the impact of Genetic Variability on Drug Target Interactions using Structural Bioinformatics (COMPLETED)	CDER	Russ Altman (Stanford)

### Special Populations Research Projects

Predicting Pediatric Dosing for Medical Countermeasures	CDER	Kathy Giacomini (UCSF)
Renal Impairment in New Drug Development: Phase II	CDER	Timothy Meyer (Stanford)
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: Reducing Literacy-related Health Disparities among Chronically Ill Adolescents	OMHHE	Lee Sanders (Stanford)
Creating a Framework for a National Adaptive Platform Trial to Evaluate Pediatric Medical Devices	CDRH	Chris Almond (Stanford)
The MUM study: MULTimorbidity and Medications: the unheard perspective of older adults	CDER	Janice Schwartz (UCSF)
Renal Impairment in New Drug Development (COMPLETED)	CDER	Kathy Giacomini (UCSF)
Comprehensive Assessment of Sex-Differential Smoking-related Effects in Publicly Available Gene Expression Data (COMPLETED)	OWH	Russ Altman (Stanford)

### COVID-19 Research Projects

A Rapid Query Model to Address Prioritized COVID-19 Questions Using EHR Data	OC	Atul Butte (UCSF)
--	----	-------------------

OneSource: SMART on FHIR for I-SPY COVID-19 Trial	CDER	Laura Esserman (UCSF)
OneSource Phase III: Demonstration of EHR/eCRF Integration in the COVID-19 Critical Care Environment	CDER	Laura Esserman (UCSF)
Learning Real-World Sex-Specific Clinical Factors Influencing the Susceptibility to Infection, Immune Response, Treatment Utilization and Outcomes Among Individuals Infected with SARS-CoV-2 Infection	OWH	Vivek Rudrapatna (UCSF) Atul Butte (UCSF)
Real-World Population Characteristics, Safety and Effectiveness of COVID-19 Vaccines	CBER	Atul Butte (UCSF)

**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
- OMMHE = Office of Minority Health and Health Equity
- OWH = Office of Women’s Health
- OHI = Office of Health Informatics
- OCS = Office of the Chief Scientist
- OC= Office of the Commissioner