



33 UCSF-Stanford CERSI Collaborative Research Projects with the FDA

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

Project Name	FDA Centers	Academic PI(s)
Patient Preferences and Patient Reported Outcomes		
PROs for Minimally Invasive Glaucoma Surgery	CDRH	Kuldev Singh (Stanford)
Pediatric Patient Preferences *	CDRH	Korey Hood (Stanford)
The Impact of Race and Ethnicity on Responses to Heart Failure PROM	CDRH	Courtney Lyles (UCSF) Urmimala Sarkar (UCSF)
PROM for Pediatric Heart Failure	CDRH	Christopher Almond (Stanford)
Patient Preferences: Upper Limb Protheses	CDRH	Leslie Wilson (UCSF)
Generic Drugs		
Effects of Excipients in Generic Drugs on Intestinal Drug Transporters	CDER	Kathy Giacomini (UCSF)
Chemoinformatic Tools to Predict the Effect of Excipients in Generic Drugs *	CDER	Brian Shoichet (UCSF)
Precision Medicine		
Role of Ancestry in Genetic Diagnostics	OHI/OCS	Snehit Prabhu (Stanford)
Causes of Real-life NGS Variability	OHI/OCS	Dmitri Petrov (Stanford)
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)
Pharmacovigilance		
Health Citizen Hospital Pilot	OHI	Ida Sim (UCSF)
Improving the Efficiency and Rigor of Pharmacovigilance at FDA *	CDER/CBER	Russ Altman (Stanford)

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Pharmacovigilance		
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)
Special Populations		
Safer Labeling of Pediatric Medications	OMH	Lee Sanders (Stanford)
Predicting Pediatric Dosing for Medical Countermeasures	CDER	Kathy Giacomini (UCSF)
Renal Impairment in New Drug Development *	CDER	Kathy Giacomini (UCSF)
Clinical Trials		
One Source	CDER	Laura Esserman (UCSF)
Developing an Operational Framework for Defining the Strength of Evidence in Therapeutic Development	CDER	Steve Goodman (Stanford)
Medical Devices		
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
Biologics		
Tissue Chips for Multipotent Stromal Cell Manufacturing	CBER	Ngan Huang (Stanford)
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)

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Biologics		
Methods to Inactivate Pathogens in Blood *	CBER	Eric Kool (Stanford)
Stem Cell Mass Cytometry *	CBER	Sean Bendall (Stanford)
Miscellaneous		
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
- CTP = Center for Tobacco Products
- OMH = Office of Minority Health
- OHI = Office of Health Informatics
- OCS = Office of the Chief Scientist