

# ***“America’s Got Regulatory Science Talent” Student Competition***

## **Tenth Annual**

Joan Adamo, PhD

University of Rochester  
Clinical & Translational Science Institute  
13 April 2023



# Tenth Annual *America's Got Regulatory Science* Talent Student Competition held on 1 March 2023

#	Team Name	Team Members	FDA Focus Areas of Regulatory Science
1	Pathogen Predictor AI	Zachary Muench, Melisanda Feliz	(2) Advanced Manufacturing (3) Artificial Intelligence
2	iDARE (Drug Availability Reporting and Expectations)	Melanie Singh	(1) Medical Countermeasures and Preparedness for Emerging Infectious Disease (3) Artificial Intelligence
3	Opi-Lock	Reshul Narhari, Stella Nantale	(1) Substance Use Disorders
4	AI Regulation for Medical Devices (AiRMD)	Joshua Jones, Sudarshan Ramanan	(3) Product Safety Surveillance (3) Artificial Intelligence (3) Use of Real-world Evidence to Support Medical Product Development and Regulatory Decision-Making
5	Team AKA	John Moyer, Connor Apa, Marianna Aviles	(3) Product Safety Surveillance (4) Patient and Consumer Preferences and Perspectives (4) Empowering Patients and Consumers to Make Better-Informed Decisions
6	Rana	Rana Alabdali	(2) Novel Technologies to Improve Predictivity of Non-Clinical Studies and Replace, Reduce and Refine Reliance on Animal Testing (2) Model-Informed Product Development (3) Artificial Intelligence
7	FoodWarn AI	Dan Farchione, Justin Jablonski	(1) Food Safety (3) Product Safety Surveillance (3) Artificial Intelligence
8	Better CAR-T Testing	Muhammad Sadeqi Nezhad	(2) Individualized Therapies and Precision Medicine (2) Novel Technologies to Improve Predictivity of Non-Clinical Studies and Replace, Reduce and Refine Reliance on Animal Testing
9	Covid Trend Tracker	John Bates, Delaney Martino, Morgan Bremer, Kee Bark	(3) Product Safety Surveillance (3) Artificial Intelligence (3) Use of Real-world Evidence to Support Medical Product Development and Regulatory Decision-Making

# 2023 Judges

**Steven Bowen, PhD**

Principal Consultant for CMC Biologics;  
DataRevive, LLC



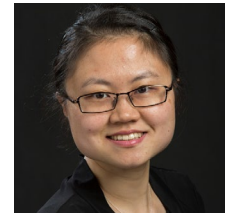
**Heather Reyes, MD, MEng**

Assistant Professor  
Department of Pediatrics, Critical Care;  
University of Rochester Medical Center



**Jenny Zhi Zheng, PhD**

Assistant Professor  
Department of Biomedical Engineering;  
Rochester Institute of Technology



<https://www.urmc.rochester.edu/clinical-translational-science-institute/education/regulatory-science-training-programs.aspx>

# 2023 FDA Advisors

## **Ryan Ortega, PhD**

Regulatory Advisor/Biomedical Engineer  
Regulatory Policy & Combination Products Staff (RPCPS)  
Office of Product Evaluation and Quality (OPEQ)  
Center for Devices and Radiological Health

## **Kimberly Schultz, PhD**

Chief, Gene Therapy Branch 2  
Division of Cellular and Gene Therapies  
Office of Tissues and Advanced Therapies (OTAT)  
Center for Biologics Evaluation and Research



## FoodTrace AI

*Dan Farchione & Justin Jablonski*



[Dan Farchione](#)



[Justin Jablonski](#)



## Opi-Lock

*Reshul Narhari & Stella Nantale*



[Reshul Narhari](#)



[Stella Nantale](#)



## iDARE (Drug Availability Reporting and Expectations)

*Melanie Singh*



[Melanie Singh](#)