“America’s Got Regulatory Science Talent” Student Competition

Tenth Annual

Joan Adamo, PhD

University of Rochester
Clinical & Translational Science Institute
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<table>
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<th>Team Name</th>
<th>Team Members</th>
<th>FDA Focus Areas of Regulatory Science</th>
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| 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 |
(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*

Opi-Lock  
*Reshul Narhari & Stella Nantale*

iDARE (Drug Availability Reporting and Expectations)  
*Melanie Singh*