University of Rochester
Ninth Annual

"America's Got Regulatory Science Talent" Student Competition

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Clinical and Translational Science Institute

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Office of the Chief Scientist

The Office of the Chief Scientist provides strategic leadership, coordination, and expertise, supporting scientific excellence, innovation and capacity to achieve FDA's public health mission.

"*America's Got Regulatory Science Talent*" Student Competition

2021
Advancing Regulatory Science at FDA:
FOCUS AREAS OF REGULATORY SCIENCE (FARS)

U.S. FOOD & DRUG ADMINISTRATION

MEDICINE of the HIGHEST ORDER

FDA Strategic Initiative	Focus Area of Regulatory Science	Regulated Product Lifecycle			
		Product Characterization, Manufacturing, and Quality	Non-Clinical Pre-market Evaluation	Clinical Pre-market Evaluation	Post-market Activities
Public Health Preparedness and Response	Medical Countermeasures and Preparedness for Emerging Infectious Diseases	✓	✓	✓	✓
	Technologies to Reduce Pathogen Contamination	✓	✓	✓	✓
	Substance Use Disorders	✓	✓	✓	✓
	Antimicrobial Resistance	✓	✓	✓	✓
	Food Safety	✓	✓		✓
	Quality of Compounded Drugs				✓
Increasing Choice and Competition through Innovation	Individualized Therapies and Precision Medicine	✓	✓	✓	✓
	Complex Innovative Trial Design			✓	
	Microbiome Research	✓	✓	✓	✓
	Novel Foods and Food Ingredients	✓	✓	✓	✓
	Regenerative Medicine	✓	✓	✓	✓
	Advanced Manufacturing	✓			✓
	Increasing Access to Generic Alternatives for Complex Drugs	✓	✓	✓	✓
	Biomarkers	✓	✓	✓	✓
	Novel Technologies to Improve Predictivity of Non-Clinical Studies and Replace, Reduce, and Refine Reliance on Animal Testing	✓	✓		
	Model-Informed Product Development	✓	✓	✓	
Unleashing the Power of Data	Product Safety Surveillance				✓
	Artificial Intelligence	✓	✓	✓	✓
	Digital Health	✓	✓	✓	✓
	Use of Real-World Evidence to Support Medical Product Development and Regulatory Decision-Making			✓	✓
Empowering Patients and Consumers	Patient and Consumer Preferences and Perspectives	✓	✓	✓	✓
	Patient-Reported Outcomes and other Clinical Outcome Assessments			✓	✓
	Empowering Patients and Consumers to Make Better-Informed Decisions				✓

2021 Focus Areas of Regulatory Science

Initiative	Public Health Preparedness and Response	Increasing Choice and Competition through Innovation	Unleashing the Power of Data	Empowering Patients and Consumers

Focus Area of Regulatory Science	• Medical Countermeasures and Preparedness for Emerging Infectious Diseases
	• Technologies to Reduce Pathogen Contamination
	• Substance Use Disorders
	• Antimicrobial Resistance
	• Food Safety
	• Quality of Compounded Drugs
		• Individualized Therapies and Precision Medicine
		• Complex Innovative Trial Design
		• Microbiome Research
		• Novel Foods and Food Ingredients
		• Regenerative Medicine
		• Advanced Manufacturing
		• Increasing Access to Generic Alternatives for Complex Drugs
		• Product Development Tools
		  • Biomarkers
		  • Novel Technologies to Improve Predictivity of Non-Clinical Studies and Replace, Reduce, and Refine Reliance on Animal Testing
		  • Model-Informed Product Development
			• Product Safety Surveillance
			• Diverse Data and Technologies
			  • Artificial Intelligence
			  • Digital Health
			  • Use of Real-World Evidence to Support Medical Product Development and Regulatory Decision-Making
				• Patient and Consumer Preferences and Perspectives
				• Patient-Reported Outcomes and other Clinical Outcome Assessments
				• *Empowering Patients and Consumers to Make Better-Informed Decisions*

FDA

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Team Name	Members	FDA Focus Areas of Regulatory Science	FDA Advisors
Yellow Jackets	Jiatong Liu, Peng Shao, Qiuyuan Qin	**3**-Use of Real-world Evidence to Support Medical Product Development and Regulatory Decision-Making	
Team WetWare	Bradley Smith	**2**-Model-Informed Product Development	
Not Your Average White Man	Sylvia Zhong, Allison Coon, Abbi Miller	**4**-Empowering Patients and Consumers to Make Better-Informed Decisions	
Lab to Leg	Stephen Wells, Hadi Wehbe, Lucas Lassinger	**2**-Individualized Therapies and Precision Medicine **2**-Regenerative Medicine; **2**-Advanced Manufacturing	
Allergen Hunters	Yuthika Shekhar, Abhijeet Talaulikar	**3**-Product Safety Surveillance; **3**-Artificial Intelligence **4**-Patient and Consumer Preferences and Perspectives **4**-Empowering Patients and Consumers to Make Better-Informed Decisions	*Tyler Peryea, ODT*
COVIDeo App Uniters	Nandita Bhowmik, Katarina Lichak, Bahie Ezzat, Ejiroghene Davies-Okarevu	**1**-Medical Countermeasures and Preparedness for Emerging Infectious Disease **4**-Empowering Patients and Consumers to Make Better-Informed Decisions	
SafeCyberTech	Sophie Mackenzie, Theo Couderc, Rebecca Mathurin	**3**-Digital Health **4**-Empowering Patients and Consumers to Make Better-Informed Decisions	
Team AiCE	Shafaqat Rahman, Blaze Strangio, Vedat Duzgezen	**2**-Individualized Therapies and Precision Medicine **3**-Artificial Intelligence	*Kevin Snyder, CDER*
Team Validity	Velia Sofia Vizcarra	**2**-Novel Technologies to Improve Predictivity of Non-Clinical Studies and Replace, Reduce, and Refine Reliance on Animal Testing	
Mask Trouble	Michael Lee, Sam Maquet	**1**-Medical Countermeasures and Preparedness for Emerging Infectious Disease **4**-Empowering Patients and Consumers to Make Better-Informed Decisions	
Smart Health Event Evaluation and Reporting (SHEER)	Mark Truskinovsky, Warish Orko	**2**-Model-Informed Product Development; **3**-Product Safety Surveillance; **3**-Artificial Intelligence	*Vinay Pai, CDRH*
FDA Databases Reimagined	Abdullah Abuomar, Helen Shammas, Terra Spurgeon	**4**-Empowering Patients and Consumers to Make Better-Informed Decisions	
Using AI to Detect Food Contamination	Catherine Xie	**1**-Medical Countermeasures and Preparedness for Emerging Infectious Disease **2**-Food Safety; **3**-Artificial Intelligence	*Betsy Yakes, Stephen Walker, Dumitru Macarisin, CFSAN*
MPS Connection	Raquel Ajalik, Rahul Alenchery, Danial Ahmad, Victor Zhang	**2**-Individualized Therapies and Precision Medicine; **2**-Model-Informed Product Development	

3rd

2nd

1st

Thanks to our 2022 judges:

Ajay Anand, PhD

Associate Professor and Deputy Director

Goergen Institute for Data Science

University of Rochester

Peggy Auinger, MS

Senior Associate Biostatistician

Department of Neurology

Center for Health + Technology

University of Rochester Medical Center

Carlos Peña, MS, PhD

Chief Regulatory Officer/Chief Quality Officer

Office of Regulatory Services

The Jacobs Institute

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

Education

PhD Program	Research Methods Forum
Faculty Career Development	Academic Research Track
Regulatory Science Training	Deaf Scientist Training
Study Coordinator Education	Bachelor's Program

More information about Education

Home

Training Resources

PhD Program

Academic Research Track (ART)

Research Methods Forum

Deaf Scientist Training

Study Coordinator Education

Regulatory Science Training Programs

Americas Got Regulatory Science Talent

Faculty Career Workshops

egulatory Science   Make a Gift

aining Programs

nd Drug Administration (FDA) have nslational Science programs to enhance the translation of research into products that benefit patients, while also improving the success rate of developing safe and effective medical products. The FDA defines Regulatory Science as "the science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of all FDA-regulated products." More information on Regulatory Science.

The UR CTSI has launched a range of programs focused on advancing training, career development and research in Regulatory Science

Advanced Certificate in Regulatory Science

The UR CTSI, in partnership with the Department of Public Health Sciences, has created an advanced certificate in regulatory science designed to produce a cadre of highly trained professionals able to contribute to the development of new medical interventions by enhancing the innovation, efficiency, and quality of the medical product development pipeline. This NYS-approved certificate covers areas of experimental therapeutics, medical product innovation, ethics, biostatistics, FDA regulatory process, intellectual property, and science, technology and health policy.

America's Got Regulatory Science Talent Competition

This annual student competition is an interactive and innovative approach to increase

Regulatory Science Portal

- Education and Training
- News and Funding Opportunities
- Institutes and Centers

Contact Us

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2022 Winning Teams

First place:

[Smart Health Event Evaluation and Reporting (SHEER)](#)

Mark Truskinovsky and Warish Orko

Second place:

[COVIDeo App Uniters](#)
Nandita Bhowmik, Katarina Lichak, Bahie Ezzat and Ejiroghene Davies-Okarevu

Third place:

[Allergen Hunters](#)

Yuthika Shekhar and Abhijeet Talaulikar

Smart Health Event Evaluation & Reporting (SHEER)

Warish Zaman Orko

Mark Truskinovsky

University of Rochester Department of Biomedical Engineering

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