

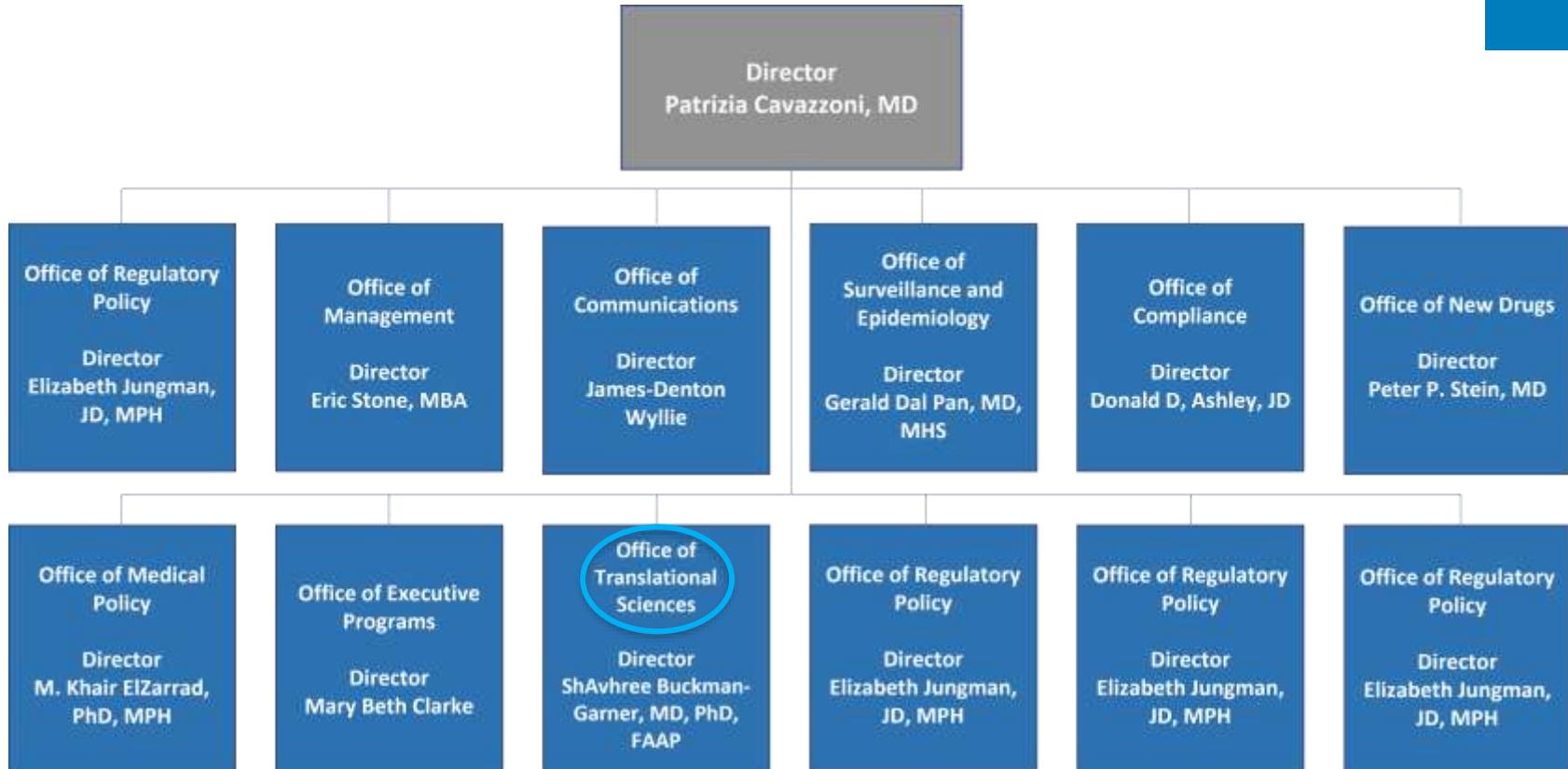


# The Office of Translational Sciences: Helping to Drive Innovation

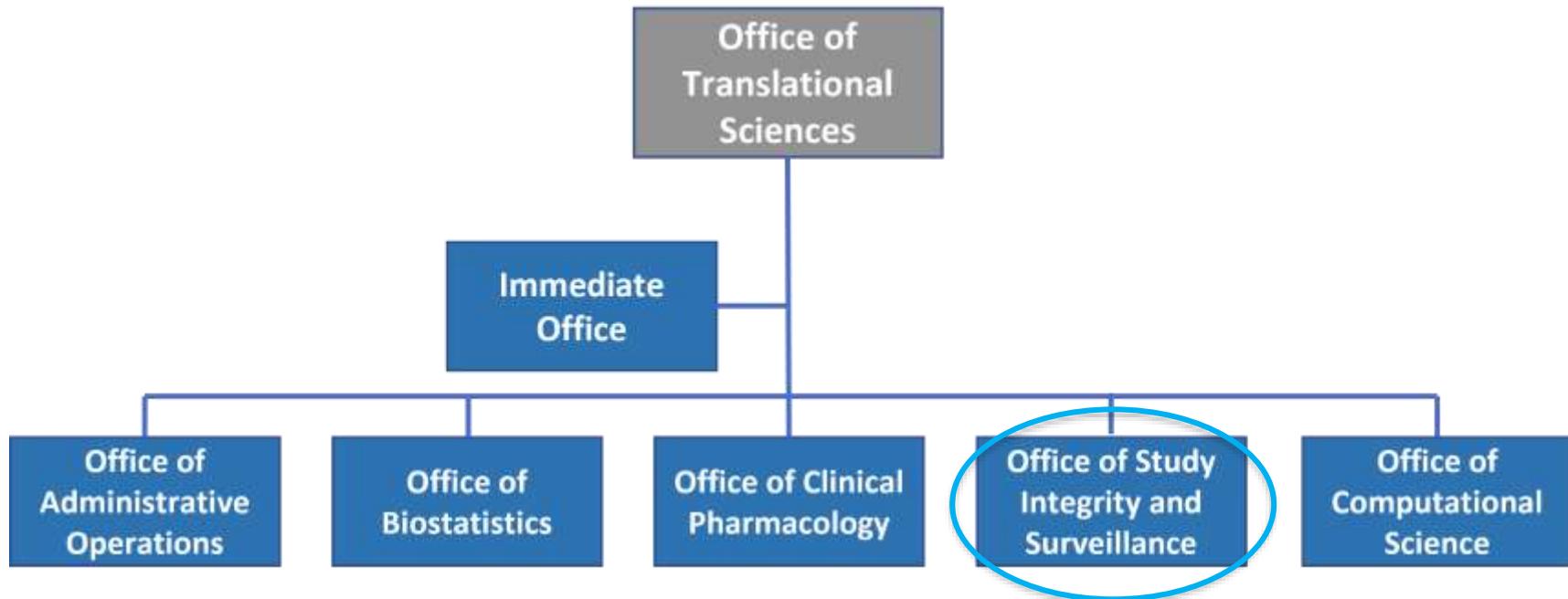
**ShaAvhrée Buckman-Garner, MD PhD**  
Director  
Office of Translational Sciences  
CDER | US FDA

[CDER Inspections of Good Laboratory Practice, Animal Rule, and  
Bioavailability/Bioequivalence Study Sites] – July 19, 2022

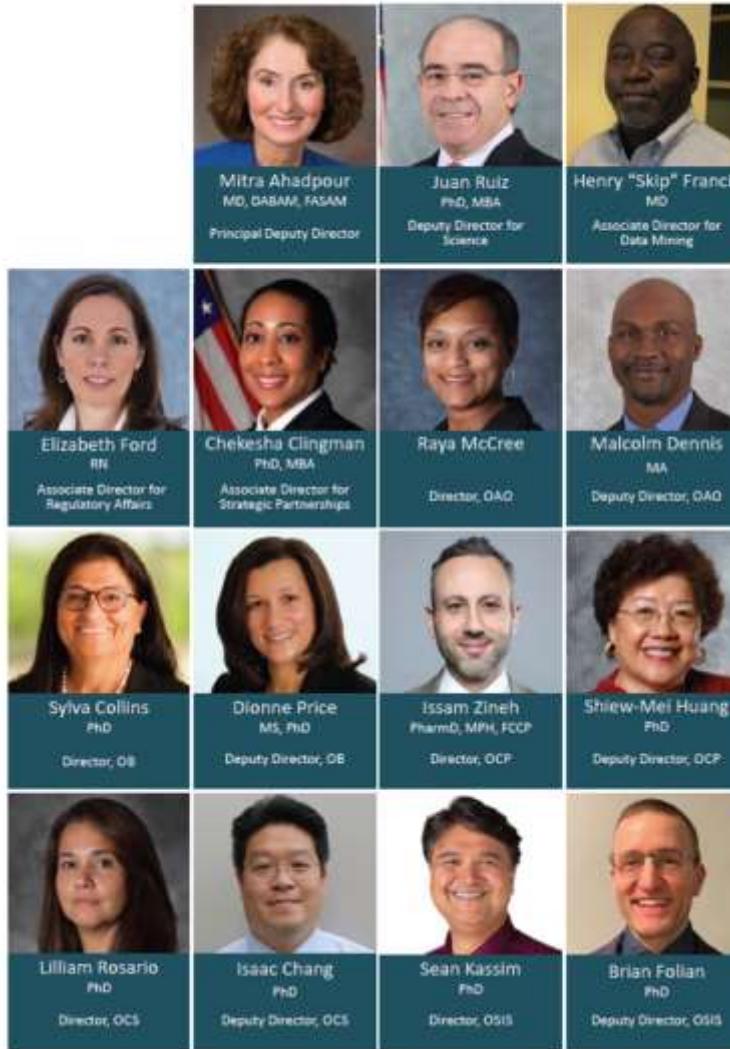
# Center for Drug Evaluation and Research



# Office of Translational Sciences



# OTS Senior Leadership



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## OUR MISSION

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We empower a diverse, collaborative, and high-performing workforce to champion innovation and advance global human drug development.

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## OUR VISION

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Driving advancements in human health through scientific and regulatory innovation.

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## OUR CORE VALUES

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ACCOUNTABILITY



LEADERSHIP



CREATIVITY/  
INNOVATION



COLLABORATION



COMMUNICATION

# OTS Efforts to Support Drug Development



Regulatory Review Capacity and Expertise



Inspectional Capacity and Expertise



Regulatory Science Research



Guidance and Policy



Stakeholder Engagement



Pilot Programs/ Innovative Approaches and Tools



Knowledge Management and Communication

# Key Points



- Bioanalysis is the foundation that supports sound drug development
- Clear standards and expectations are critical for reliable analytical results
- Quality and integrity of data is paramount
- We have to be open to new approaches/innovation
- Continued dialog and transfer of knowledge on science and technology between stakeholders to enhance the application review and inspection process

