

The Office of Translational Sciences: Helping to Drive Innovation

ShaAvhrée Buckman-Garner, MD PhD

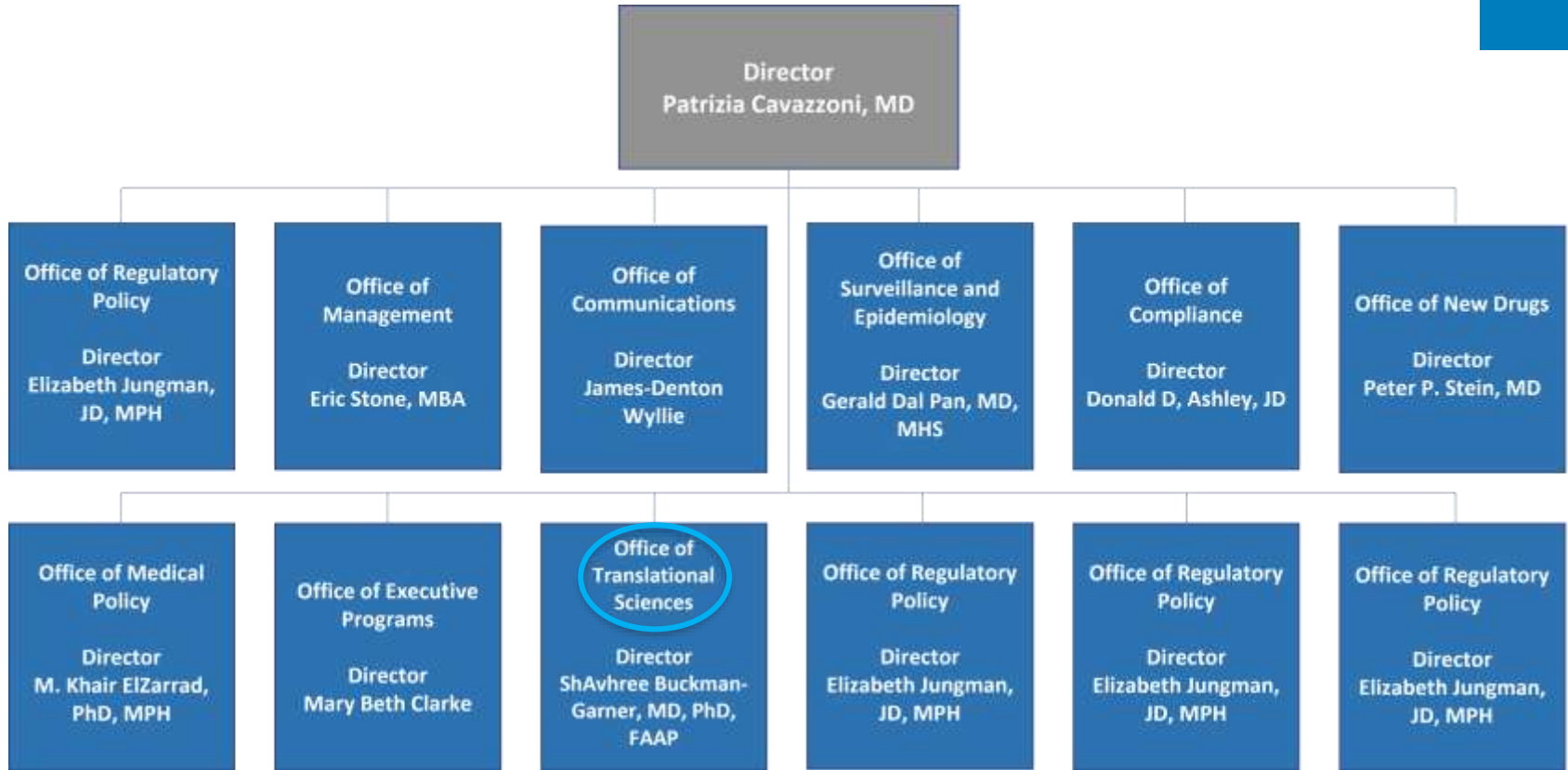
Director

Office of Translational Sciences

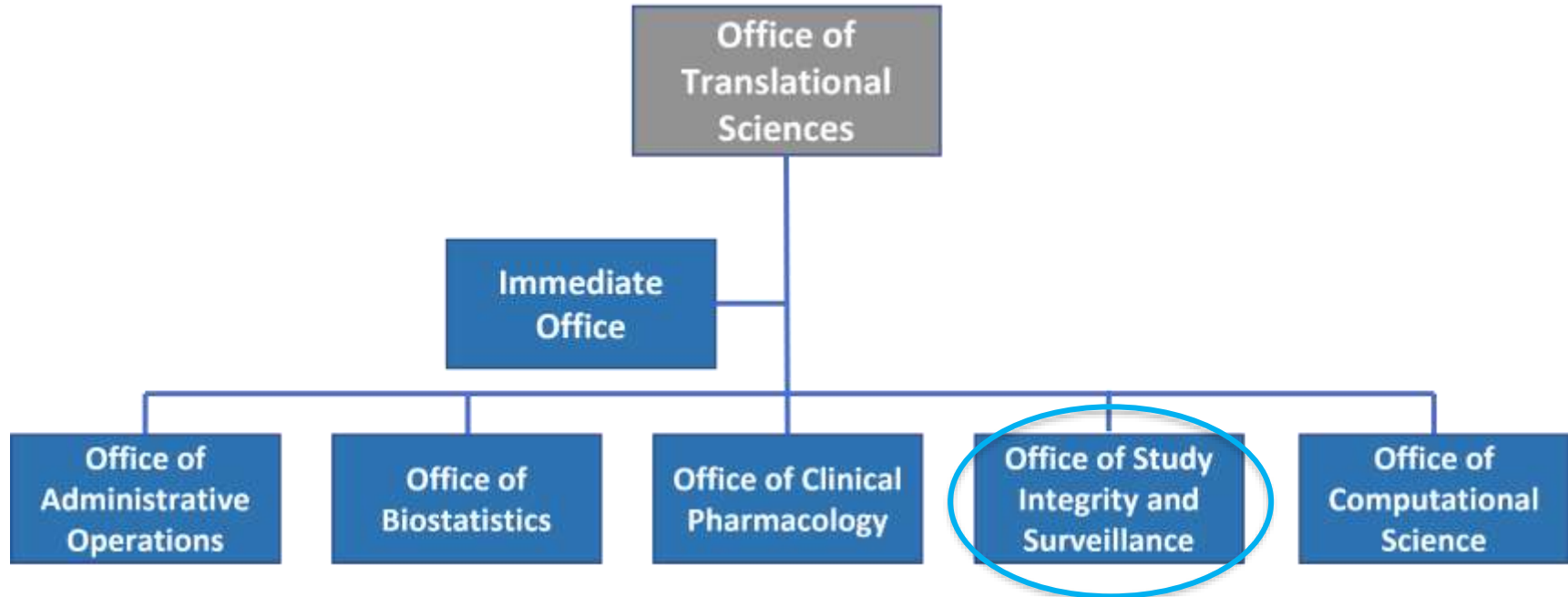
CDER | US FDA

[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



Mitra Ahadpour
MD, DABAM, FASAM
Principal Deputy Director



Juan Ruiz
PhD, MBA
Deputy Director for
Science



Henry "Skip" Francis
MD
Associate Director for
Data Mining



Elizabeth Ford
RN
Associate Director for
Regulatory Affairs



Chekeshia Clingman
PhD, MBA
Associate Director for
Strategic Partnerships



Raya McCree
Director, OAO



Malcolm Dennis
MA
Deputy Director, OAO



Sylvia Collins
PhD
Director, OIB



Dionne Price
MS, PhD
Deputy Director, OIB



Issam Zineh
PharmD, MPH, FCCP
Director, OCP



Shiew-Mei Huang
PhD
Deputy Director, OCP



Lilliam Rosario
PhD
Director, OCS



Isaac Chang
PhD
Deputy Director, OCS



Sean Kassim
PhD
Director, OGIS



Brian Follan
PhD
Deputy Director, OGIS

OUR MISSION

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

OUR VISION

Driving advancements in human health through scientific and regulatory innovation.

OUR CORE VALUES



ACCOUNTABILITY

LEADERSHIP

CREATIVITY/
INNOVATION

COLLABORATION

COMMUNICATION

OTS Efforts to Support Drug Development





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



U.S. FOOD & DRUG
ADMINISTRATION