

The Office of Translational Sciences: Helping to Drive Innovation

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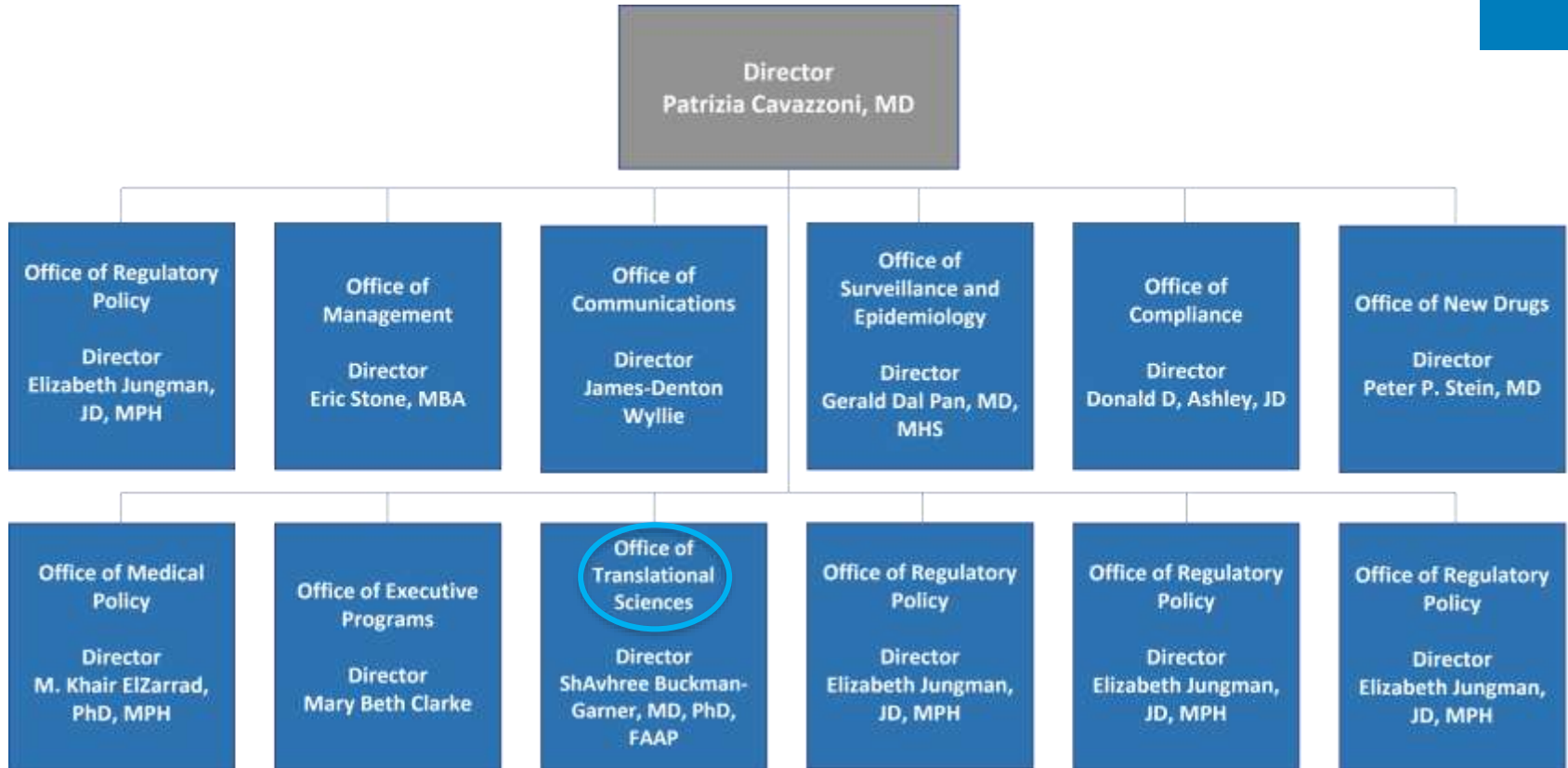
Director

Office of Translational Sciences

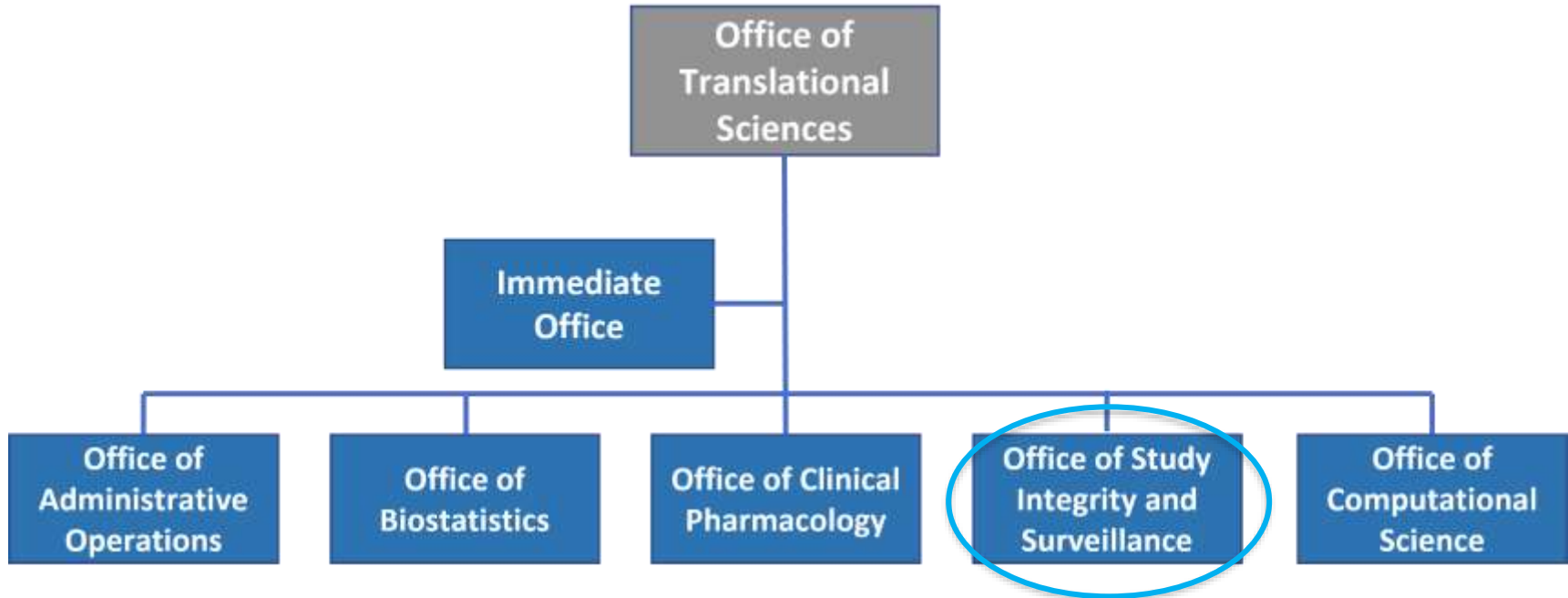
CDER | US FDA

[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



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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

