Overview of Lifecycle Management in OCP

Ethan M. Stier, RPh, PhD
Associate Director for Lifecycle Management (LCM)

Disclaimer

This presentation reflects the views of the presenter and should not be construed to represent FDA's views or policies

Agenda

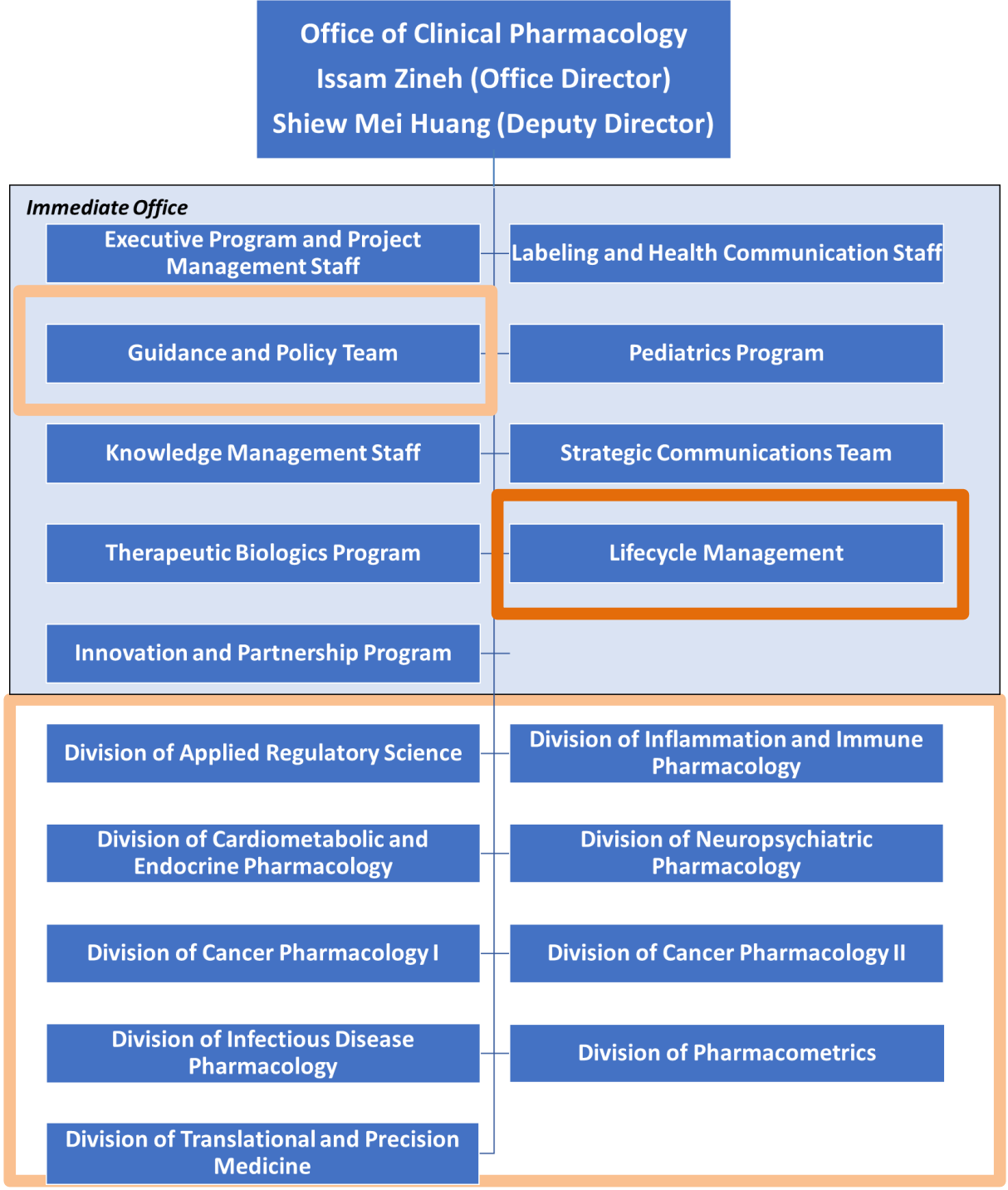
- What Lifecycle Management (LCM) means from a Clinical Pharmacology perspective?
- Describe relationship of LCM to OCP and CDER stakeholders
- Define scope of issues in LCM

What is Role of Lifecycle Management in Clinical Pharmacology?

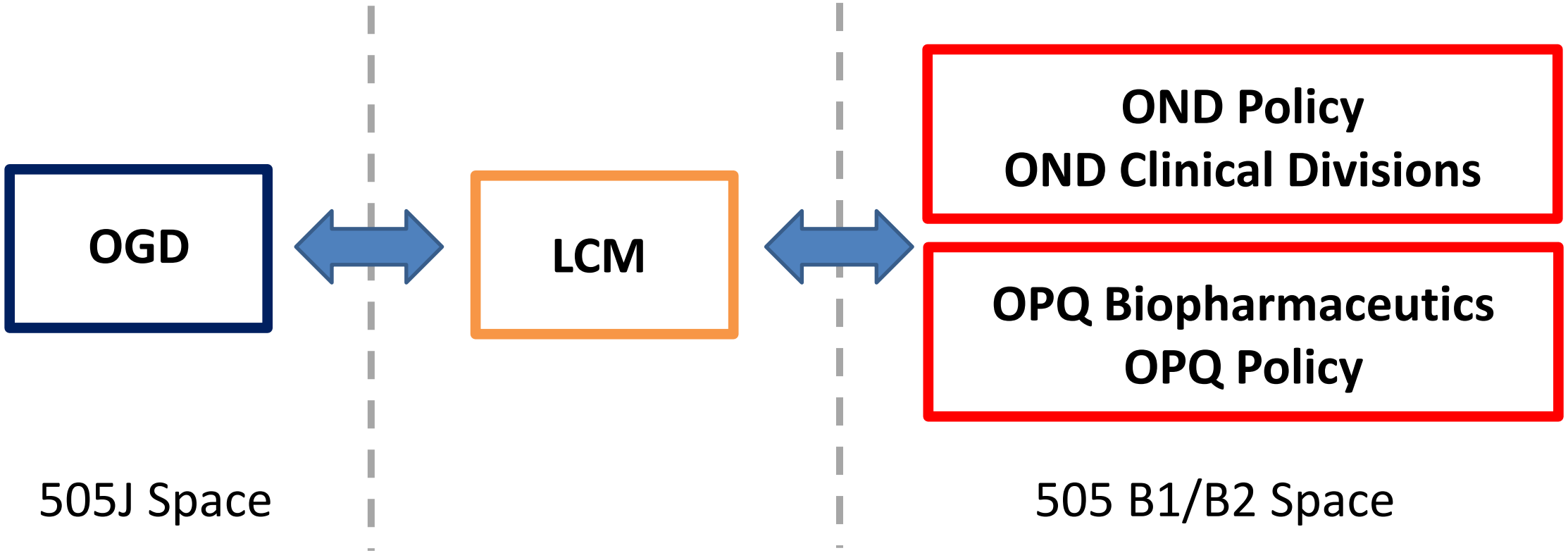
Advance the scientific and policy decision making for patient-centered, drug product review decisions* throughout the product lifecycle

*Examples of review decisions include bridging formulations, new populations, new dosage forms

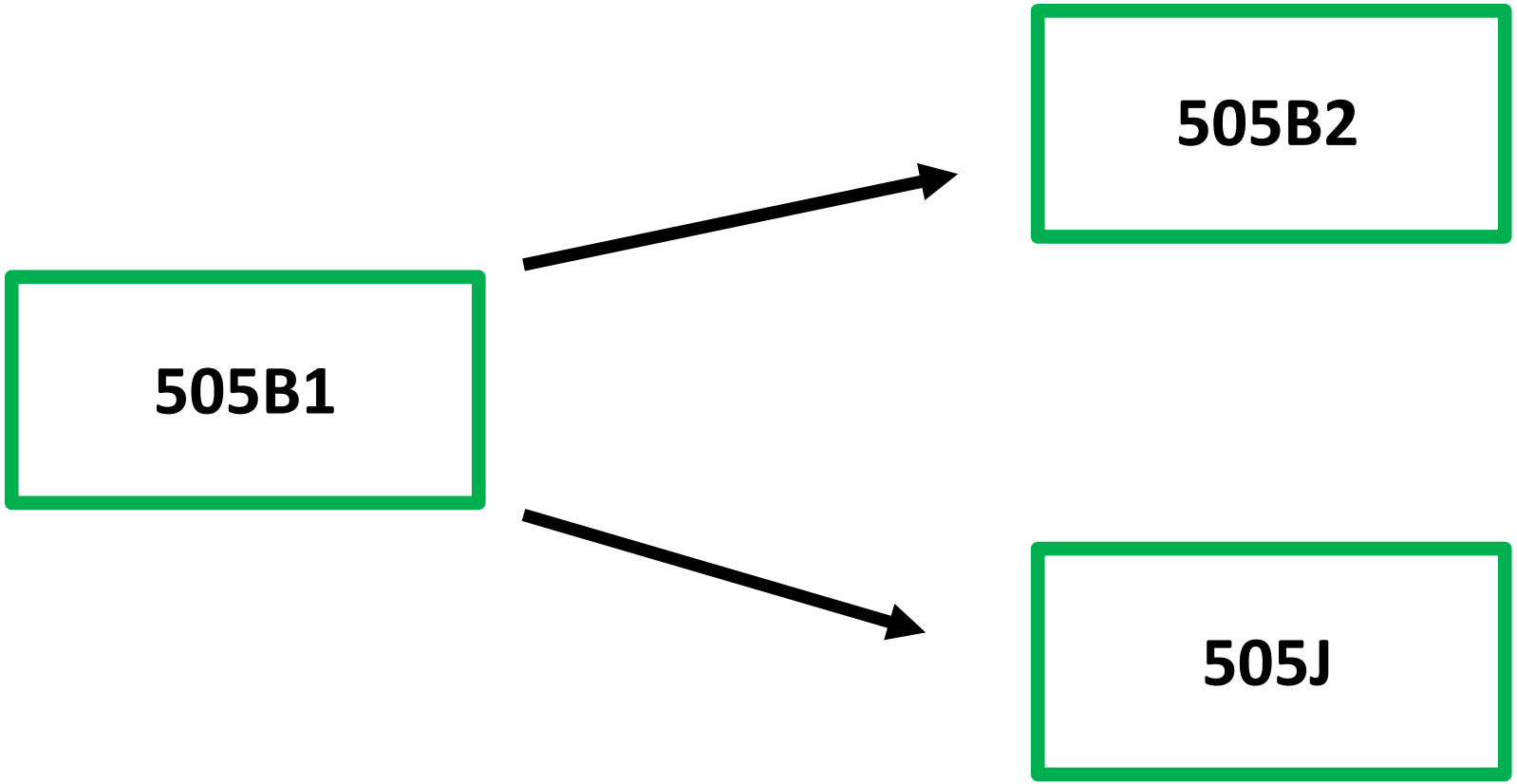
LCM OCP Stakeholders



LCM CDER Stakeholders



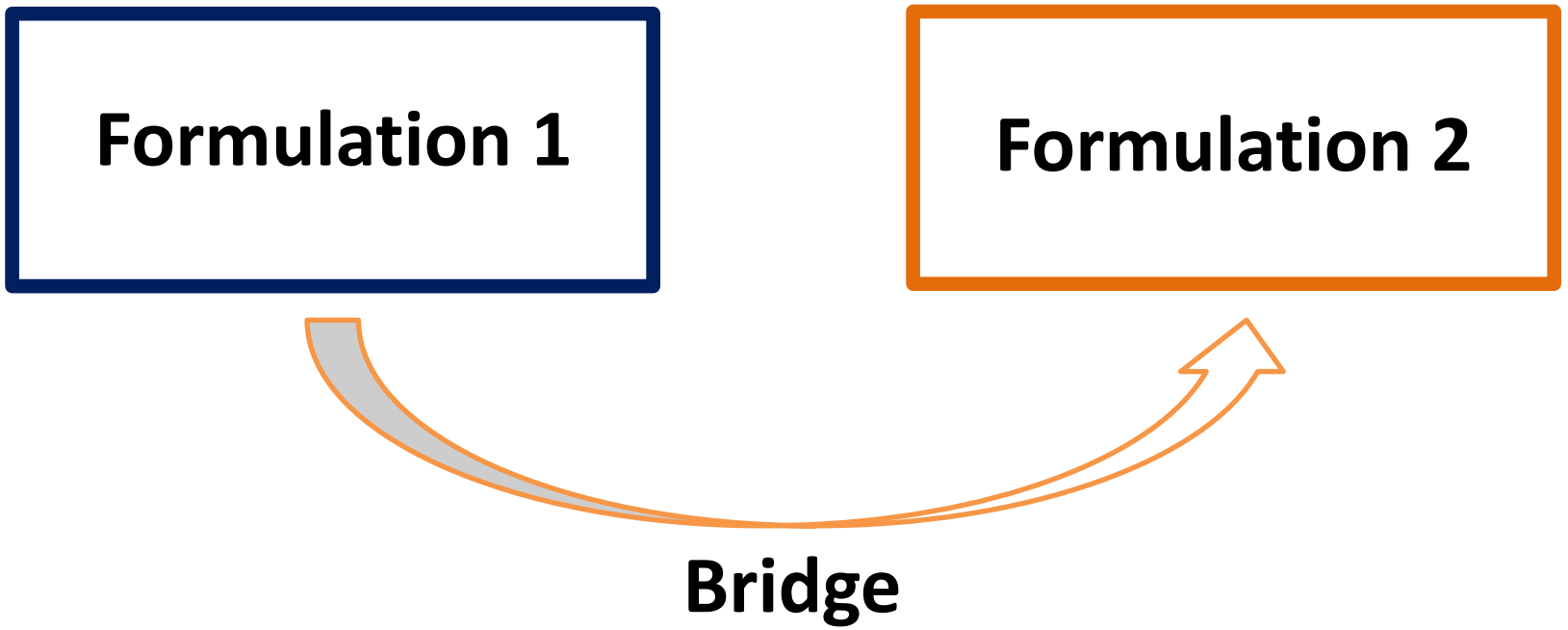
Lifecycle Scope in Small Molecule Space



Lifecycle Decisions

Clinical trial formulation	To be marketed formulation	Alternative route	Site change
Polymorph/salt change	Modified release	New population	Food effect

Advancing Policy and Science to Make Lifecycle Decisions



Thank You

- Paul Seo
- Raj Madabushi
- Anu Ramamoorthy
- Daphne Guinn
- Mongthuong Tran
- Roger Nosal
- Xavier Pepin
- Jim Polli
- Kimberly Raines
- Hao Zhu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