

# **Oncology Therapy Development Workshop: Pivotal Steps and Avoiding Pitfalls for Start-ups**

---

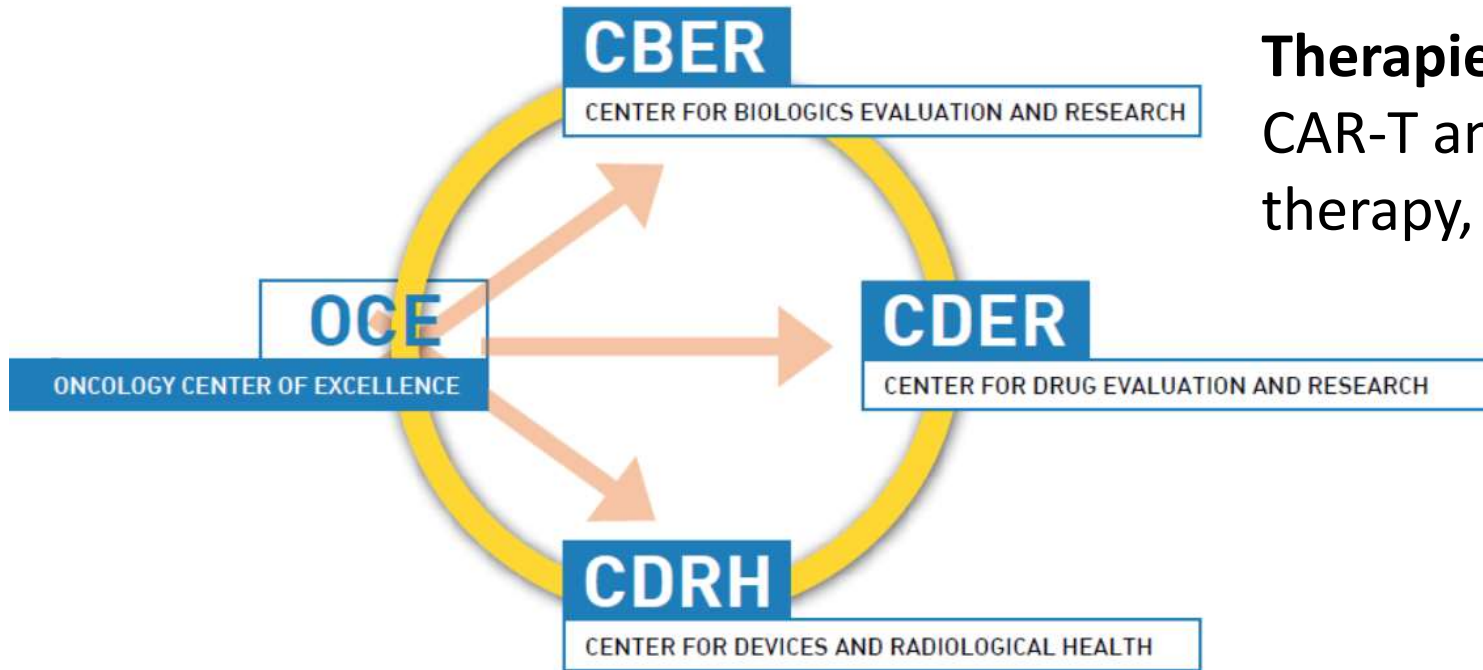
**Marc Theoret, MD**

Deputy Director, Oncology Center of Excellence  
U.S. Food and Drug Administration

March 30, 2021

# FDA Oncology Center of Excellence (OCE)

The Oncology Center of Excellence fosters unified interaction between 3 FDA centers



## Office of Tissues and Advanced Therapies (OTAT)

CAR-T and other cellular therapies, gene therapy, therapeutic vaccines

## Office of Oncologic Diseases (OOD)

Small molecules, monoclonal antibodies, antibody-drug conjugates

## Office of Invitro Diagnostics and Radiological Health

Companion and complementary diagnostics

# Oncology Center of Excellence

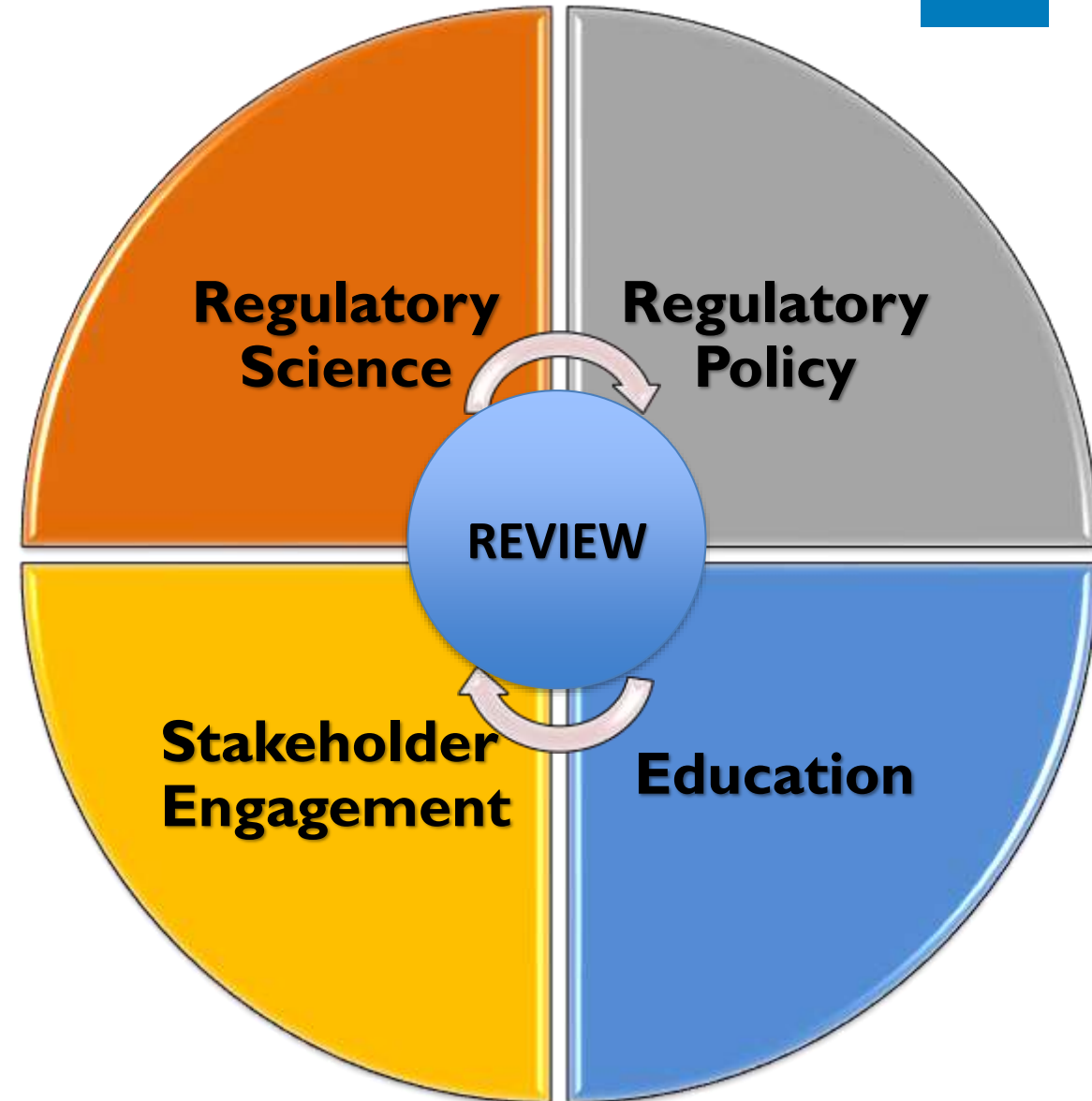


## OCE Mission:

To achieve patient-centered regulatory decision-making through **innovation** and **collaboration**.

## OCE Vision:

To create a **unified** and **collaborative** scientific environment to advance the development and regulation of oncology products for patients with cancer



# Examples of OCE Projects

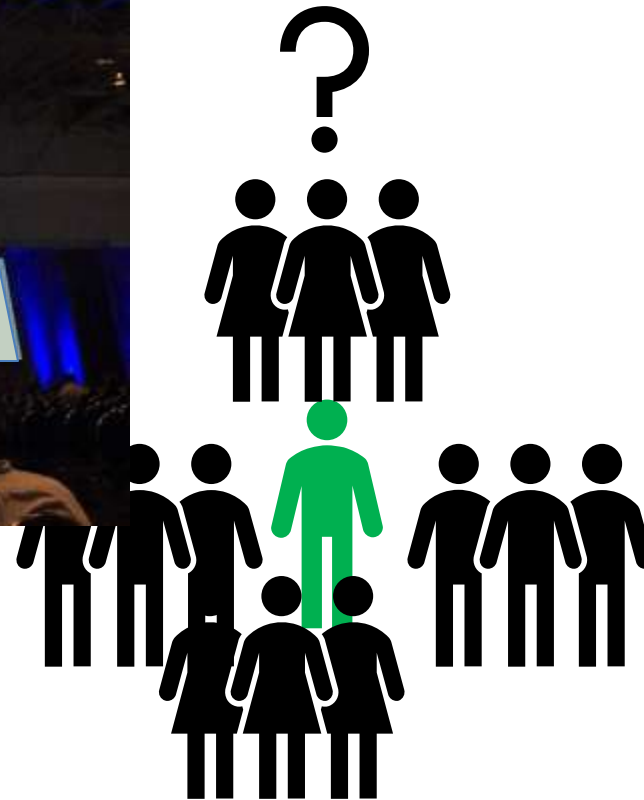


Project	• Community
Project	• Facilitate
Project	• Orbis
Project	• Equity
Project	• Silver
Project	• PatientVoice
Project	• Renewal
Project	• Socrates
Project	• SignifiCanT
Project	• Post Covidity
Project	• Catalyst

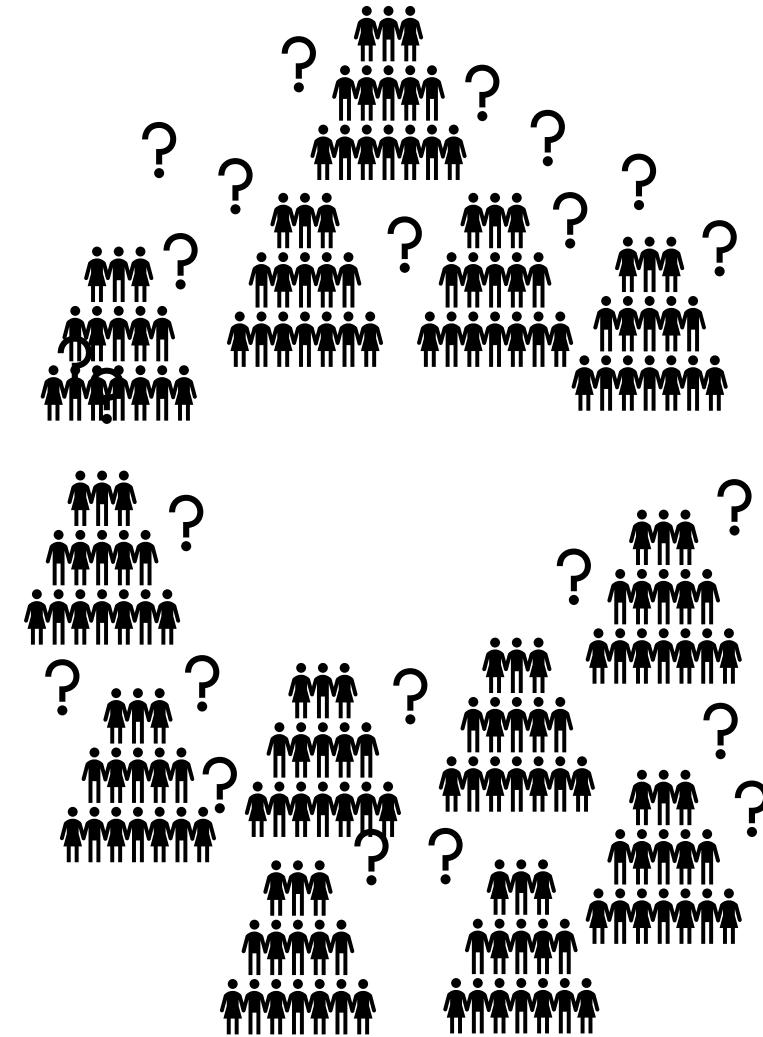
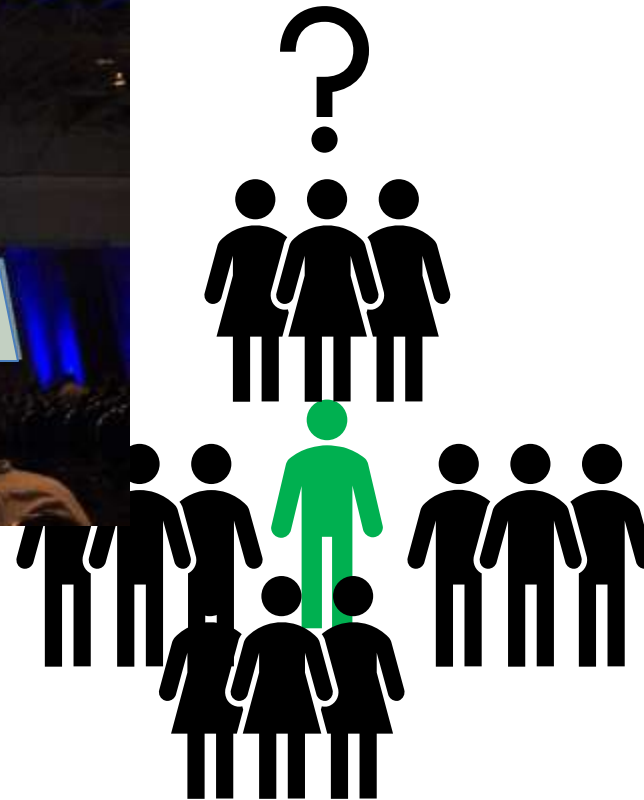
# OCE: Project Catalyst



# OCE: Project Catalyst



# OCE: Project Catalyst





# OCE: Project Catalyst

