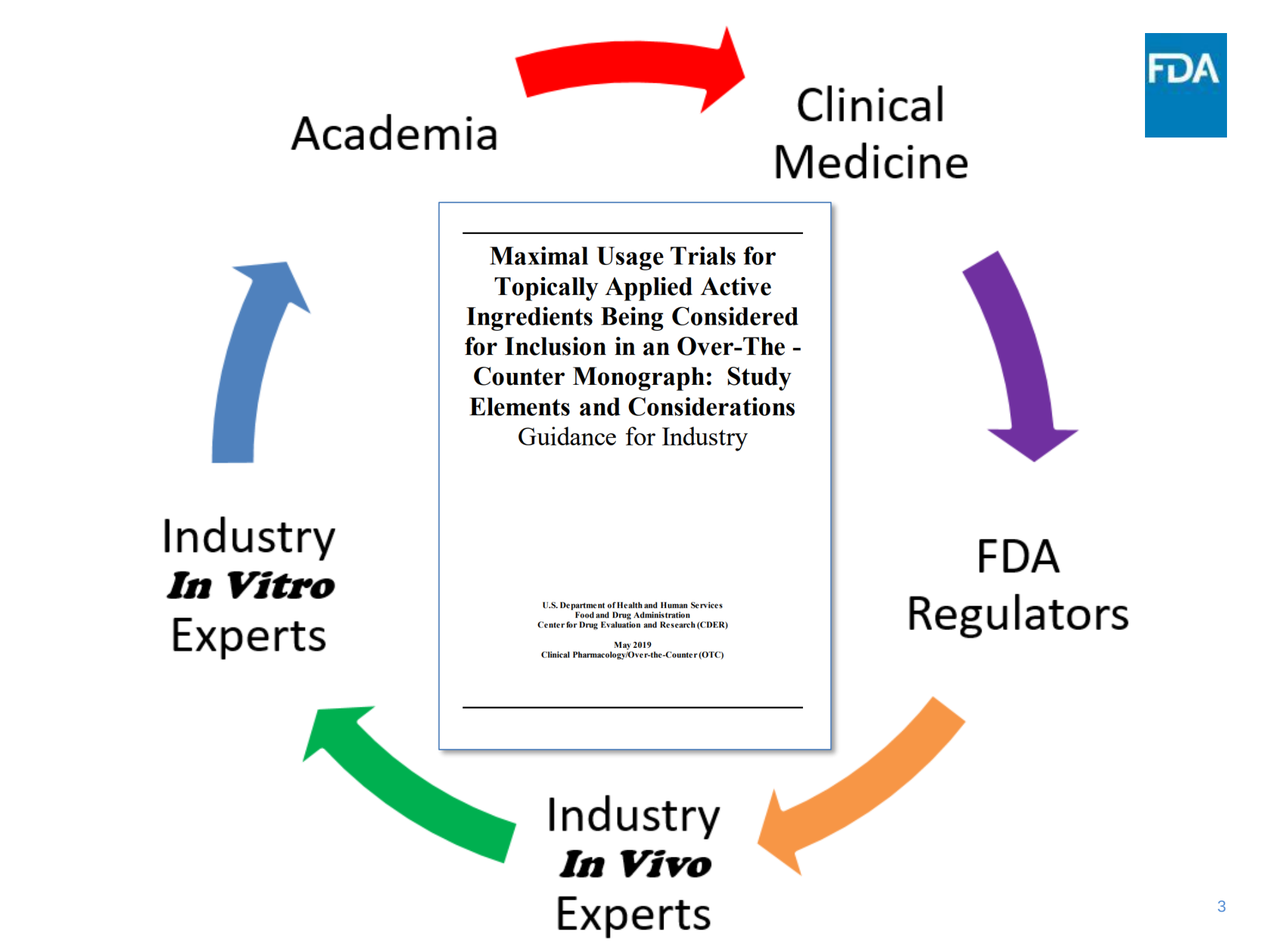
Welcome


FDA U.S. FOOD & DRUG ADMINISTRATION
FDA/M-CERSI Workshop:
Topical Drug Development —
Evolution of Science and Regulatory Policy
July 29–30, 2019
University of Maryland School of Pharmacy
Baltimore, MD

Program Objectives

1. To present the background of the current regulatory policy in the area of dermal absorption and its underpinnings.
2. To provide examples of the successful incorporation of both in vivo (Maximal Usage Trials) and in vitro (percutaneous permeation studies, i.e., IVPT) in drug development.
3. To facilitate discussion as to the design elements and concerns of both in vivo and in vitro methods in the new drug and over-the-counter drug space.
4. To stimulate discussion between interested parties in the evolution of science in the area of topical drug development and dermal absorption testing.


Academia
Clinical Medicine
Maximal Usage Trials for Topically Applied Active Ingredients Being Considered for Inclusion in an Over-The - Counter Monograph: Study Elements and Considerations
Guidance for Industry
U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
May 2019
Clinical Pharmacology/Over-the-Counter (OTC)
Industry
In Vitro
Experts
FDA
Regulators
Industry
In Vivo
Experts

Speakers-Organizers-Moderators

- E. Dennis Bashaw, PharmD*
- Audra Stinchcomb, PhD*
- Sheila Fallon Friedlander, MD
- Murali Matta, PhD
- Theresa Michele, MD
- Vijendra Nalamothu, PhD
- Luke Oh, PhD
- Vivek Purohit, PhD
- Sam Raney, PhD
- Leandro L. Santos, M.Sc.
- Soo Hyeon Shin, PhD
- Chinmay Shukla, PhD
- Jane Sohn, PhD.
- Nathalie Wagner, M.Sc.
- Sojeong Yi, PhD
- Da Zhang, PhD

*organizers