

Committee for the Advancement of Clinical and Scientific Education (CACSE):
Annual Abrams Lecture:
Challenges Developing a Topical, On Demand, & Behaviorally-Congruent HIV Prevention Product
June 5, 2019, 1 PM-2:30 PM
WO Building 2, Room 2031

Series Description

The Committee for the Advancement of Clinical and Scientific Education lecture series (CACSE) gives the FDA scientific community and health professionals the chance to stay current with advances in therapeutics and applied scientific data in various clinical fields, as well as to hear the perspectives of scientists and clinicians on the application of regulatory scientific knowledge.

The Committee for the Advancement of Clinical and Scientific Education (CACSE) creates a venue to discuss the cutting-edge technologies and therapeutic advances in various scientific and clinical areas.

Session Description

Additional choices for HIV pre-exposure prophylaxis, beyond oral daily PrEP, remain an acute need for persons at risk of HIV infection. One approach entails providing a topical rather than systemic, on demand rather than long-term daily or long-acting, and congruent with existing peri-coital behaviors rather than require new behaviors. The session will chronicle one approach to tackle each of these product development challenges in developing a rectal microbicide for HIV pre-exposure prophylaxis.

References

Carballo-Dieguez A, Giguere R, Lentz C, Dolezal C, Fuchs EJ, Hendrix CW. Rectal Douching Practices Associated with Anal Intercourse: Implications for the Development of a Behaviorally Congruent HIV-Prevention Rectal Microbicide Douche. *AIDS Behav.* 2018 Nov 10. doi: 10.1007/s10461-018-2336-6.

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Leyva FJ, Bakshi R, Fuchs EJ, Li L, Caffo BS, Goldsmith AJ, Carballo-Dieguez A, Ventuneac A Du Y, Leal J, Lee LA, Torbenson MT, Hendrix CW. Iso-osmolar enemas demonstrate preferential gastrointestinal distribution, safety, and acceptability compared with hyper- and hypo-osmolar enemas as a potential delivery vehicle for rectal microbicides. *AIDS Res Hum Retroviruses* 2013 Nov;29(11): 1487-1495. PMC3809953

Hiruy H, Fuchs EJ, Marzinke MA, Yue C, Caffo B, Spiegel HML, Rohan LC, McGowan I, Hendrix CW. A Phase 1 Randomized, Blinded Comparison of the Pharmacokinetics and Colonic Distribution of Three Candidate Rectal Microbicide Formulations of Tenofovir 1% Gel with Simulated Unprotected Sex (CHARM-02). *AIDS Res Hum Retrovir* 2015 November 31(11):1098-1108. PMC4651050

Hoang T, Date AA, Ortiz JO, Young TW, Bensouda S, Xiao P, Marzinke MA, Rohan LC, Fuchs EJ, Hendrix CW, Gumber S, Villinger F, Cone RA, Hanes J, Ensign LM. Development of rectal enema as microbicide (DREAM): Preclinical progressive selection of a tenofovir prodrug enema. *Eur J Pharm Biopharm* 2018 May 23. pii: S0939-6411(18)30476-4.

Series Objectives:

- Explain the therapeutic research conducted at the FDA
- Discuss the cutting-edge technologies and advancements in the science underlying the many professions contributing to the FDA regulatory science.

Learning Objectives After completion of this activity, the participant will be able to:

1. Describe the clinical methods required to enable the development of a rectally-administered topical product designed for local action
2. Give examples of early phase clinical studies guided by human-centered design built around peri-coital behaviors in order to prevent rectal acquisition of HIV.