



# Issues in the development of long-acting PrEP: An investigator's perspective

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Long-Acting/Extended Release ARV Research Resource Program (LEAP)





# The Big Picture

- LA/ER technology is changing rapidly, with new approaches likely to be available for clinical testing in the next 1-3 years:
  - Implants
  - Transdermal microneedle patches
  - Long-acting oral formulations
  - Combination ARV's plus hormonal contraception
- There is increasing competition for participants in PrEP trials, as well as expanded PrEP demonstration projects, in high-income countries.
- Wider availability of generic ARV's (e.g., coformulated TDF/3TC) may create economic pressures for health care providers to provide daily oral PrEP.
- Guaranteed access to SOC greatly complicates Phase 3 clinical prevention trials.

<http://longactinghiv.org>

**leap**»

Long-Acting/Extended Release Antiretroviral Resource Program

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### Who We Are

Funded by an R24 grant from the National Institutes of Health, the mission of LEAP is 3-fold:

1. To support scientific innovation through investigator access to broad-based scientific expertise including the pharmaceutical industry.
2. To develop a communications and data hub to support investigators in this field
3. To provide a Modeling and Simulation Core Service that helps investigators identify the most promising approaches to the development of new products.

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### Funding Opportunities

Finding funds for research can be a challenge. The following resources are provided to help guide your

**workshop**

November 6 - 7, 2017



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## **Long Acting/Extended Release Antiretroviral Formulations**

for Children, Adolescents, and Pregnant Women:  
**Knowledge Gaps and Approaches for Development**

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**National Institute of  
Allergy and  
Infectious Diseases**  
Division of Acquired  
Immunodeficiency Syndrome

**NIAID Conference Center**  
5601 Fishers Lane, Room 1D13 . Rockville, MD 20852



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# LEAP Pediatrics Workshop: Major Recommendations

- Clinical trials must include children, adolescents, and pregnant women from an early stage, using a parallel rather than sequential approach to drug development and approval. There are several ways in which the research agenda can be tailored to generate, in a timely and ethical manner, the data necessary for regulatory approval of these formulations for pregnant women and children of all ages.
- Pediatric studies covering all age groups should be planned from the outset, and if possible should be carried out concurrently, and as soon as adult safety and efficacy data are available.
- Efforts should be made to include adolescents in adult clinical trials, and to establish adolescent-specific trials only when necessary.



## Acknowledgements

### FUNDING SOURCES AND PARTNERS

- NIAID
  - R24 AI-118397
  - IMPAACT Network
- NICHD
- Johns Hopkins University
- University of Liverpool
- Bill and Melinda Gates Foundation
- Clinton Health Access Initiative