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

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The Big Picture

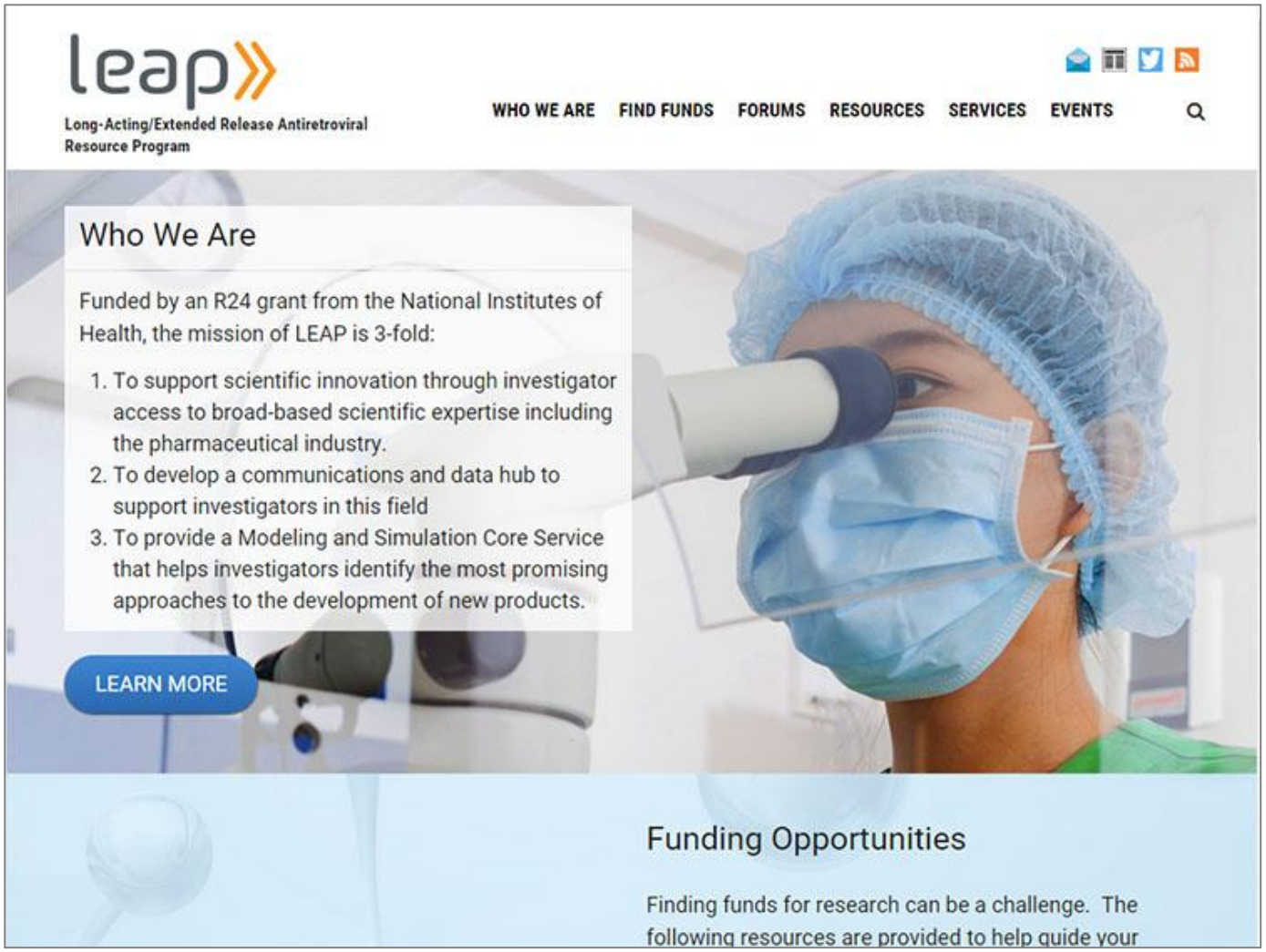
- LA/ER technology is changing rapidly, with new approaches likely to be available for clinical testing in the next 1-3 years:
  - Implants
  - Transdermal microneedle patches
  - Long-acting oral formulations
  - Combination ARV's plus hormonal contraception

- 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



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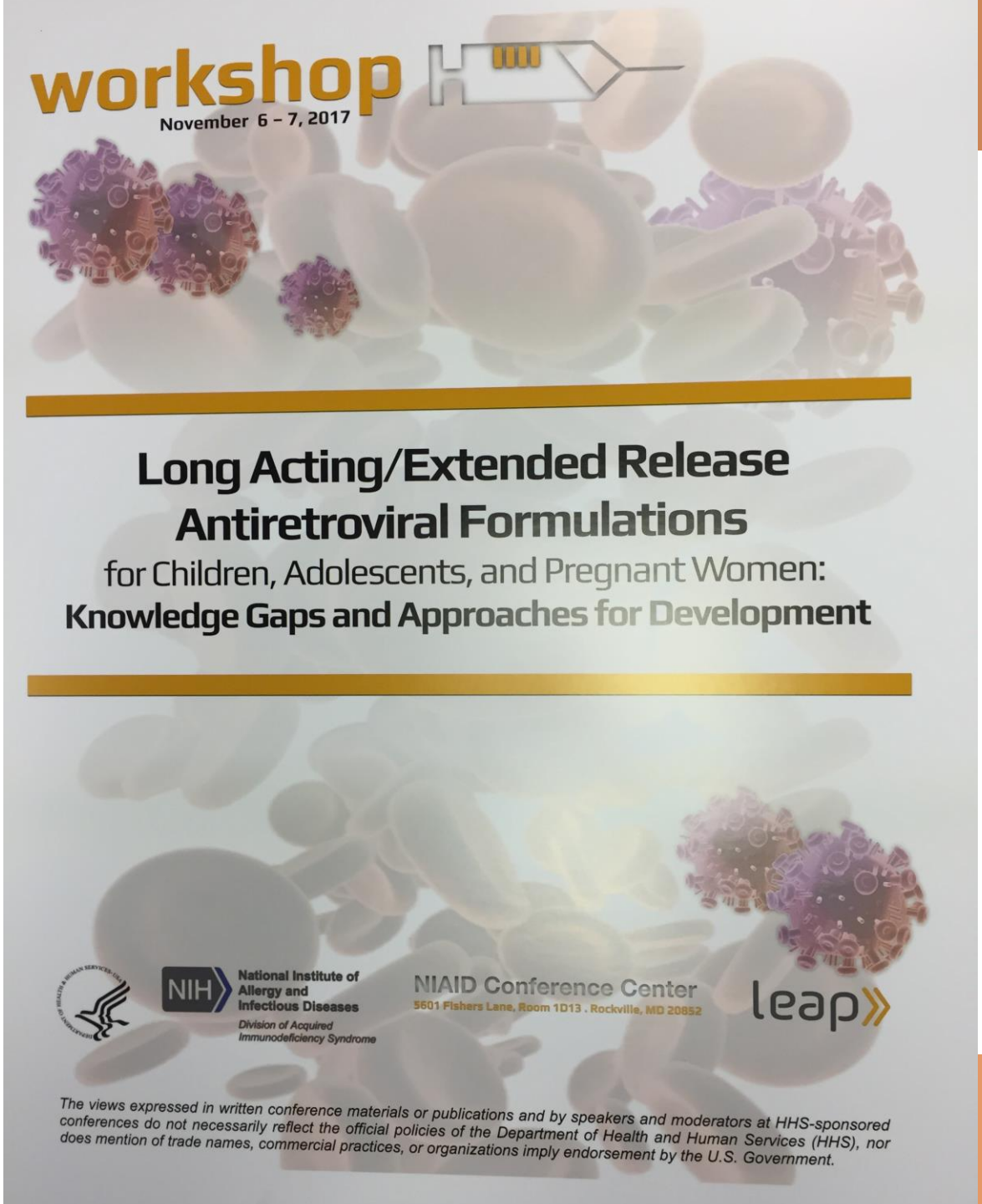
workshop
November 6 – 7, 2017
Long Acting/Extended Release Antiretroviral Formulations
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LEAP Pediatrics Workshop: Major Recommendations

- 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.

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