

# LA PrEP and Youth

- What and how much data are needed for adolescent minors to consent for their participation in clinical trials of LA PrEP?
- What minimal data from clinical trials in minors are needed to support potential licensure for LA PrEP to prevent HIV in at-risk adolescents?
  - PK/PD
  - Safety & tolerability/acceptability
  - Use patterns & adherence
  - Risk behaviors
- Among these, what has been demonstrated to be a significant challenge in youth and what will be the impact on LA PrEP studies in adolescents?
- Are any or all of the above data acceptable if only obtained from HIV-infected adolescent minors?

# LA PrEP for neonates

- What are the dose optimization challenges and considerations?
  - Unique PK / PD (distribution, metabolism, elimination, etc)
  - Physiology and anatomy not linear with age; Weight-based dosing
  - Formulation (release rate, large volume, etc); acceptability & tolerability
  - Safety issues (novel toxicities, pain perception, etc)
  - Needs to cover breastfeeding
- Are efficacy trials needed or possible, given the current landscape?