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?