



# Accelerating access to LA ARV formulations and DDS for HIV prevention and treatment

## Challenges and Opportunities – Panel Discussion

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# Disclosures

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No conflict of interest regarding the content of this presentation

# CONRAD is a non-profit biomedical R&D organization



**Mission:** To improve **global health** through the development of **innovative, user-centered** technologies

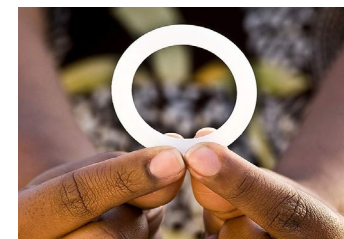
**Current areas** of focus: **prevention** of HIV/STIs, unintended pregnancies, and maternal and neonatal disease



**Nested** within EVMS and **funded** by public sector, philanthropic, and private sector organizations

# Long-acting drug delivery systems and formulations for HIV prevention and treatment

- ❖ Daily oral ARV-based regimens for PrEP and ART are highly effective if properly used
- ❖ Multiple factors (behavioral, structural, biological) make consistent use and adherence challenging
- ❖ This is especially true for AGYW, who are at the core of the epidemic in SSA
- ❖ LA, less user dependent formulations and DDS have the potential to improve adherence, uptake and coverage, and intervention success



# LA DDS for HIV prevention and treatment Opportunities

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- ❖ Increase method/product choice
- ❖ Increase acceptability (e.g. convenience, discreetness), uptake, continuation, and coverage
- ❖ Increase adherence
- ❖ Decrease PK fluctuations (better safety and efficacy profile)
- ❖ Decrease clinic visits and monitoring
- ❖ Potential to decrease cost
- ❖ Potential to increase cost-effectiveness



# LA DDS for HIV prevention and treatment

## Challenges - Development

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- ❖ High R&D demands
  - Depends on API physico-chemical properties and potency; few molecules with adequate characteristics
  - DDS are typically more complex
  - Entails long preclinical and IND enabling studies and timelines, including characterization of PK tail
  - More complicated regulatory process
  - Requires development/validation of accelerated methods to characterize release rates in vitro and qualify clinical supplies
- ❖ High bar for safety (persists for long time in the body)
  - Side effects
  - Concurrent infections (e.g. TB)
  - DDIs
- ❖ Need for oral short-acting lead in or bridging between dosing or tail coverage
- ❖ Need for user friendly formulations and systems
- ❖ Long term stability and shelf life
- ❖ Low cost of goods, storage and distribution; especially in LMICs
- ❖ Higher developmental cost and investment



# LA DDS for HIV prevention and treatment Challenges – Implementation and access

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Desirable characteristics:

- ❖ Low health care system demands (e.g. regarding HCP training; number and length of clinic visits; need for specialized tests); demedicalizing and decentralizing service delivery
- ❖ Comprehensive understanding of end-user/HCP/stakeholders preferences and needs in different contexts and countries
- ❖ Ease of manufacturing; local manufacturing
- ❖ Overall low cost (availability of generic products)
- ❖ Ease of distribution (no cold chain preferable); diversification of channels
- ❖ Integration with existing HC infrastructure
- ❖ Broad access

# Panel discussion on challenges and opportunities

## Starting questions

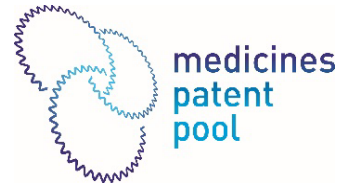
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- What has been the most challenging step in the R&D process of the long-acting ARV products recently approved or currently in clinical development?
- In terms of product attributes, what are the expectations for, and most important features of, new long-acting ARV formulations, especially from the policy makers, implementers and community (end-user) perspectives?
- How can new long-acting ARV formulations be developed, what product attributes should be considered, to facilitate implementation in low-resource settings?



# Acknowledgements

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**PEPFAR**

U.S. President's Emergency Plan for AIDS Relief

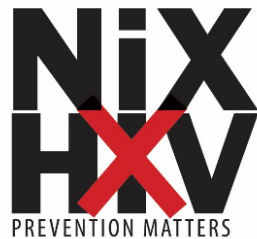


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