Prevention Field Landscaping: Update on 3rd Desktop Review – 1 Jan-30 June 2023

SC August 11, 2023 Ariane van der Straten







Desktop Review

- Why:
- ✓ MATRIX Prime required to monitor R&D activities in the HIV prevention and microbicide research space: Partners Calls + Desktop Review
- Desktop prevention landscape review (excluding vaccines and antibody mediated approaches): formal report submitted to USAID biannually
- How:
- ✓ Publications/abstracts reviews via PubMed, Bio and Medrxiv, conferences websites/attendance, listserves and database review.
- ✓ Published reviews, reports and media releases on relevant topics
- ✓ Current NIH-funded projects (via NIH RePorter)



Key Points

- Third biannual landscaping (Jan 1-June 30, 2023) submitted to USAID July 10, 2023.
- No significant overlap with current MATRIX CP projects identified.
- 64 projects total/ 41 active (HIV prevention and MPTs)
 - 6 new projects identified this round
 - 1 new NIAID award (MPT refillable implant, PIs: Grattoni & Stayton)
- 37 publications/presentations in first half of 2023.



Highlights of Projects

# and types of projects	N	Active/ Ongoing	Currently not active/unknown status
HIV Prevention only	34	23*	11
MPTs	30	18**	12
TOTAL	64	41	23

- (*) 3 new entries for HIV Prevention only
- (**) 3 new entries for MPTs





HIV prevention projects (N=34)

- Projects stopped/completed/of unknown status (N=11)
 - 5 projects stopped due to safety signals/ API development abandoned
- Active Projects (n=23)

3 new entries:

- New Publication on MAP+ bictegravir (QUB)
- New Publication on ISFI+ model drug zidovudine+ D-peptide (QUB) [covalently conjugation for rapid hydrogel formation + long-acting drug release achieved via hydrolysis of the covalent bond under physiologic conditions]
- NIAID funded Lactobacillus vaginal tablet with mCV-N (Osel)*

Drugs investigated (highlights)

- Repurposed ARVs approved for treatment (e.g., bictegravir, lenacapavir),
- New unapproved ARVs for prevention usage (e.g., MK8527)
- Non-ARVS: small molecule HIV entry inhibitor

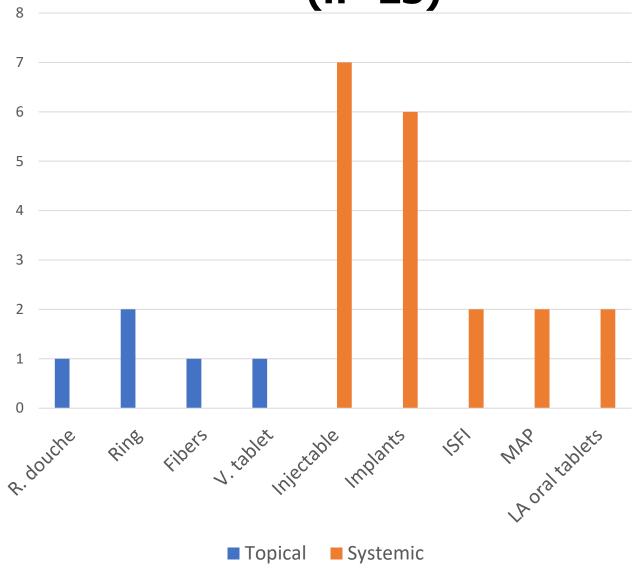




HIV Prevention only

- Majority of LA DDS
- Majority of systemic DDS (19)
- 8 projects at clinical stage (FIH to phase III)
- 4 projects use non-ARV drugs







MPT projects (N=30)

- Projects stopped/completed/of unknown status (N=12)
- Active Projects (n=18)

3 new entries:

- nanoMPI: Newly funded NIAID R01 for a refillable implant with ISL+ENG drugamer (HMRI + UW)
- HIV+GC prevention ring: Ongoing NIAID funding for dual purpose ring with TDF (for HIV PrEP) and a monoclonal antibody to prevent GC (U.Mass)-
- DPP with with TAF/FTC (for HIV PrEP) and LNG/EE (for contraception) (PopC + Medicines360 funding)-
- Drugs investigated (highlights)
- ARVs (e.g. TFV/TDF/TAF, ISL, DLG) & non-ARV (e.g., Q-GRFT, mAB for HIV prevention
- Hormonal (e.g., LNG, EE, ENG) & non-hormonal (e.g., AB, copper) for contraception
- ISL-ENG drugamer



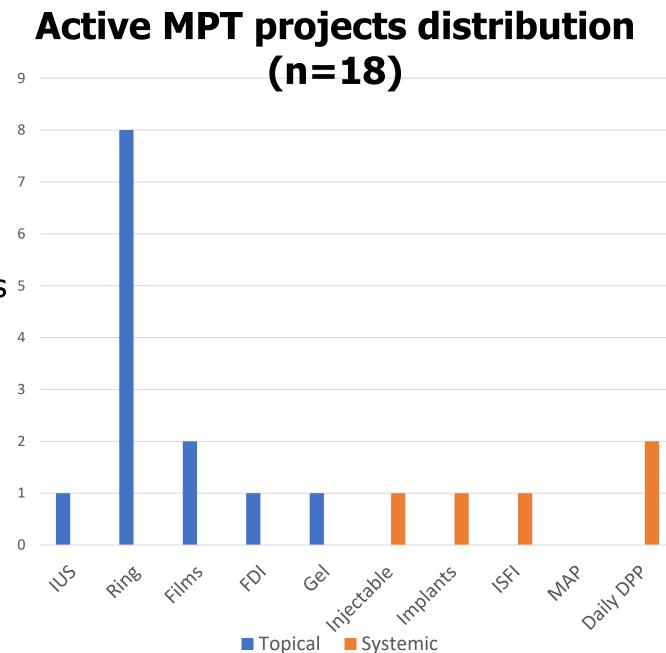


MPT projects

- Majority are topical products (13)
 - 8 ring projects
- 5 projects at (early) clinical stage
- 3 systemic LA-DDS
- 12 dual purpose prevention projects 5
 - 11 projects HIV+ PREG
 - 1 project HIV+GC/NG

Prevention indications:

- HIV- all 18 (by definition)
- Pregnancy: 17 projects
- HSV: 5 projects
- GC/NG: 3 projects
- HPV: 2 projects



37 publications/presentations thru 6/30

LA-DDS:

- Preclinical (NHP) efficacy of 2 ISL implants, CAB-ISFI and LEN injectables
- Assessment of <u>toxicity/safety issues</u> with novel ARVs/DDS: TAF/implants; oral ISL for PrEP
- Extended (3-month) duration of protection of Cab-LA in CGW
- <u>Safety/acceptability</u> of 3-month MPT rings (TFV and TFV/LNG) & 1 month Dapi ring in Pregnant/BF women

On demand DDS:

- Safety& PK of TAF/EVG FDI (rectal/vaginal) in males and females-
- Extended vaginal protection of TAF/EVG FDI as PEP in NHP model
- <u>Safety</u> of Q-GRFT rectal douche



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