Tenofovir/Emtricitabine Bioequivalence Following Ingestible Sensor Co-encapsulation

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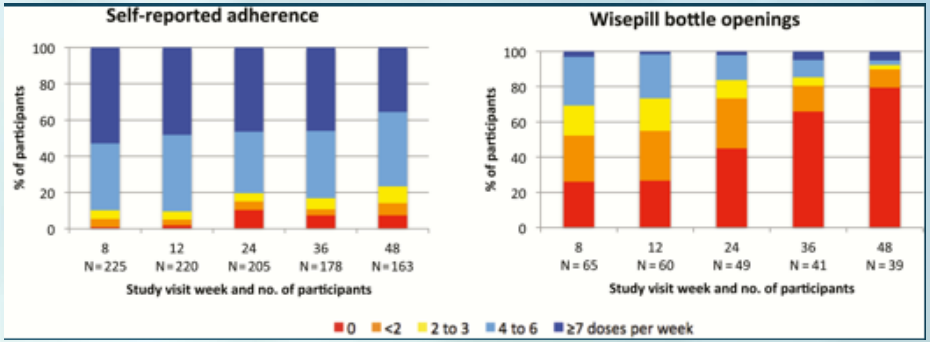
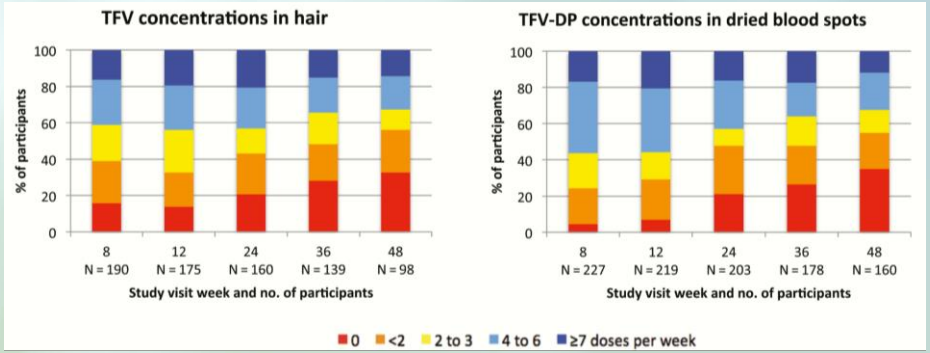
Conflict of Interest

None to disclose

Adherence in YMSM

- **MSM account for 70% of all new HIV infections**
  - **27% of new infections in YMSM 13-24 years**
- **Young age is correlated with lower adherence**
  - **iPrex demonstrated lower PrEP efficacy (28%) in YMSM compared to older participants (56%)**





Koss et al. 2017

Current Approaches

- Limitations in current methods: lack of precision, “white-coat adherence”, dependence upon patient participation/engagement, and difficult implementation

- TFV-DP concentrations

- Proteus Discover

How Proteus Discover Works

FDA APPROVED

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The sensor sends a signal to the patch as it passes through the stomach.

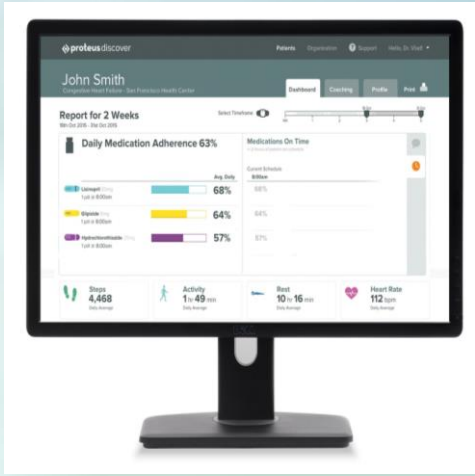
The patch sends this information to the app along with records of steps, activity rest and heart rate.

The app allows patients to see how they are doing and share this with their healthcare team via the portal.

DigiMeds™

Wearable patch

Discover app



Discover portal

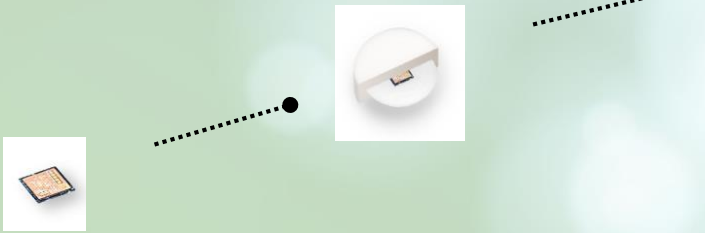
Used by patients

Used by healthcare teams

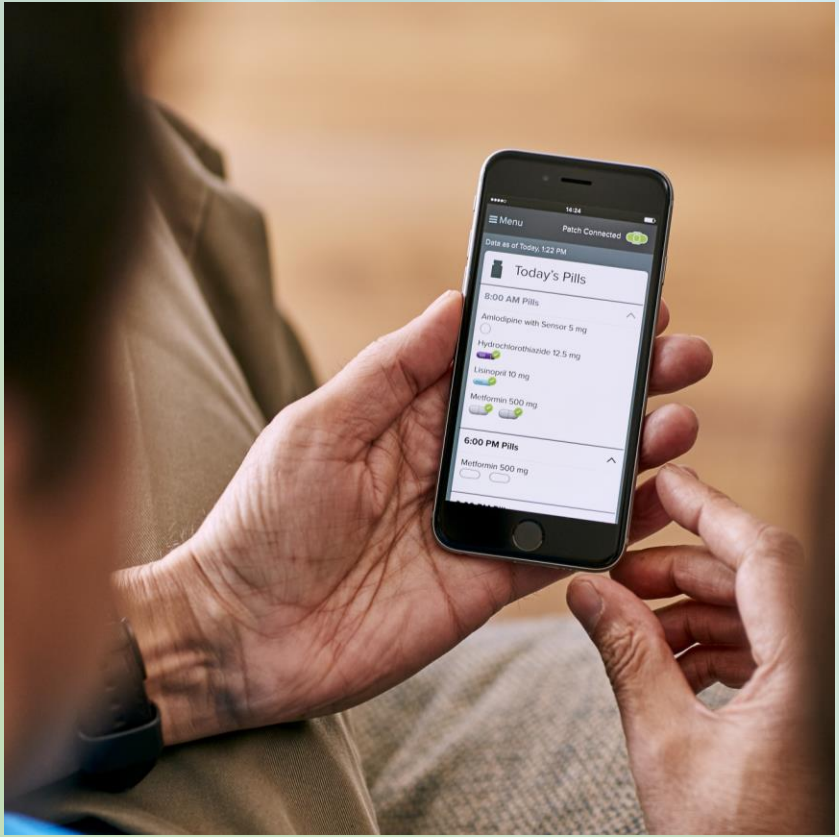
Co-encapsulated with each medication

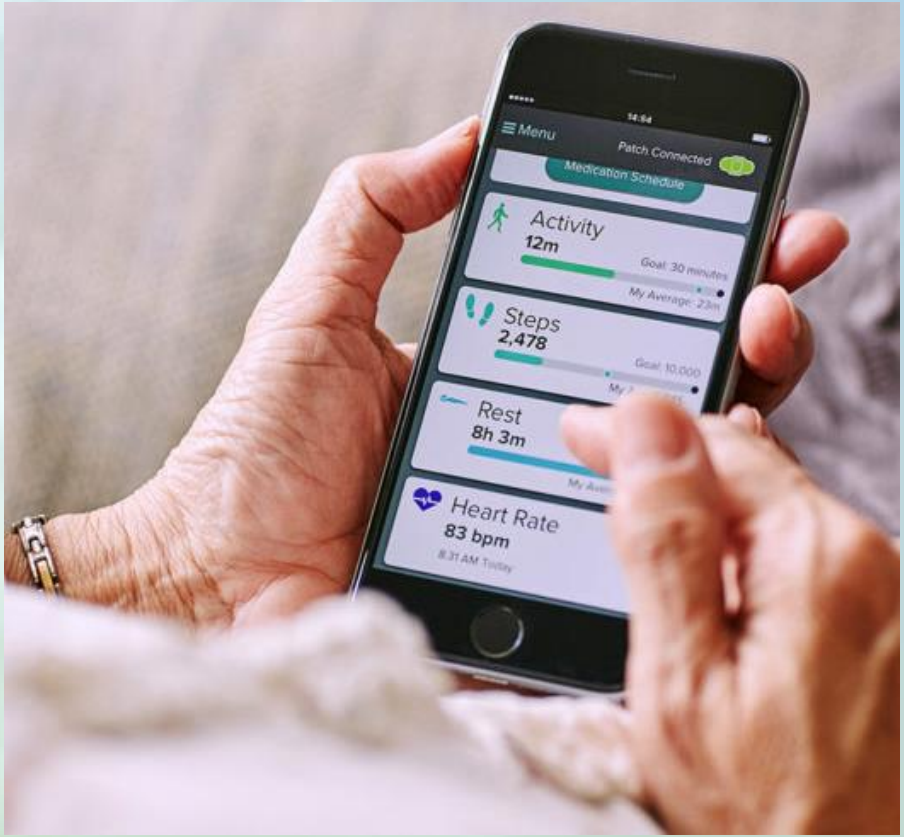
On order of a physician, a pharmacist puts a Proteus sensor inside a capsule, along with each dose of a patient's prescribed medication.

A tiny sensor is placed inside a small pill.



The sensor contains tiny amounts of silicon, copper and magnesium that pass through the body naturally, just like the fiber in food.


Menu
Patch Connected
Data as of Today, 1:22 PM
Today's Pills
8:00 AM Pills
Amlodipine with Sensor 5 mg
Hydrochlorothiazide 12.5 mg
Lisinopril 10 mg
Metformin 500 mg
6:00 PM Pills
Metformin 500 mg

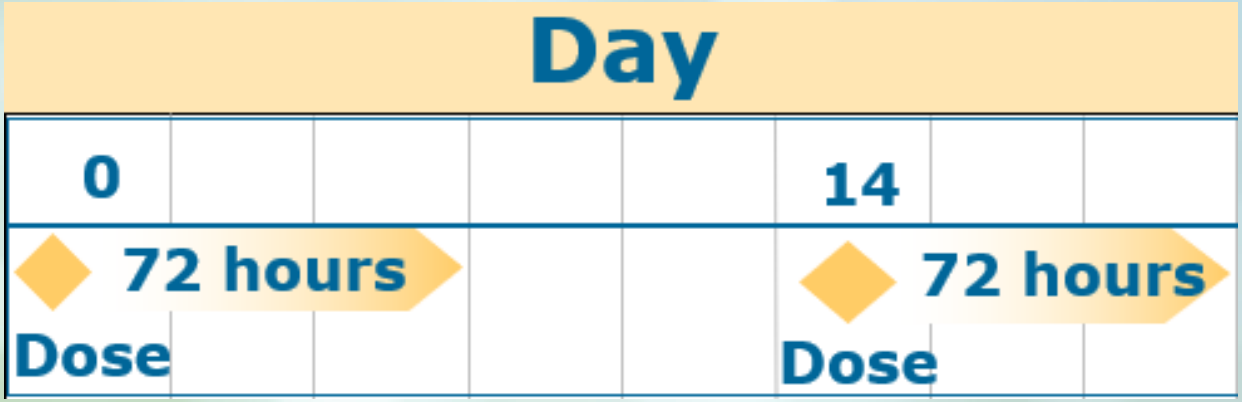

Menu
Patch Connected
Medication Schedule
Activity
12m
Goal: 30 minutes
Steps
2,478
Rest
8h 3m
Heart Rate
83 bpm

Study Objective

Determine bioequivalence between TDF/FTC encapsulated with ingestible sensor versus unencapsulated TDF/FTC

Methods

- **Randomized, cross-over study of 24 participants**



- **Non-compartmental analysis of AUC, C_{max} and $t_{1/2}$**

Bioequivalence

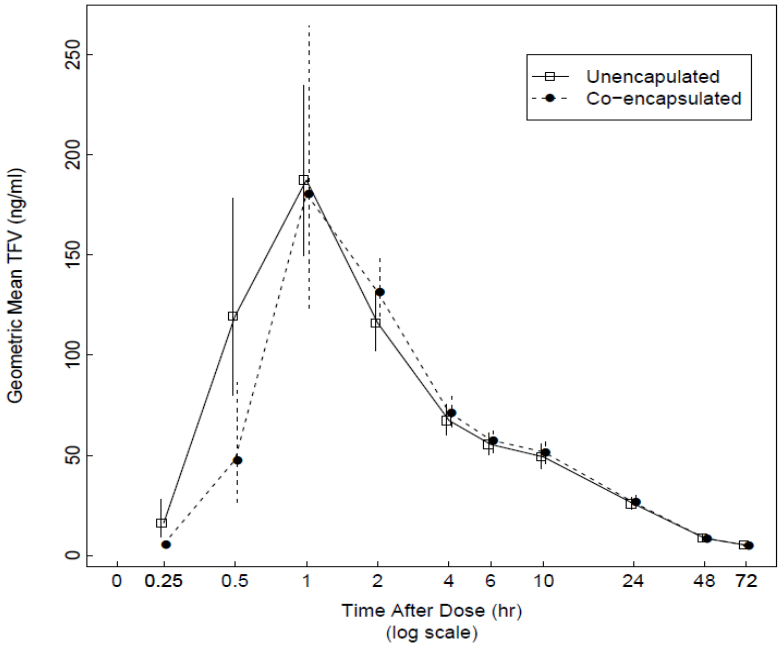
Bioequivalence is defined as the 90% confidence interval (CI) of geometric mean ratio of AUC and C_{max} being within 80%-125%

Patient Demographics

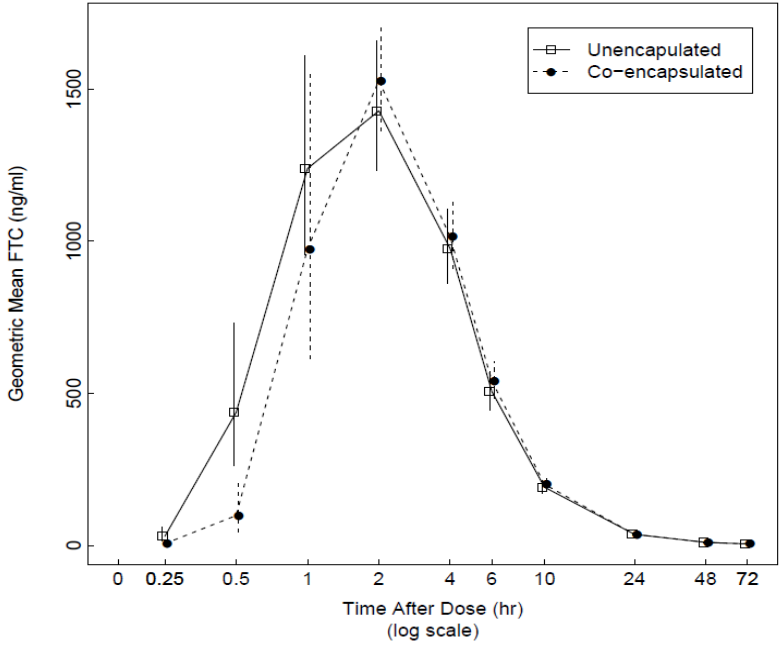
	N=24
Sex, n(%) Male Female	 11 (46%) 13 (54%)
Race/Ethnicity, n(%) White Black Hispanic	 19 (79%) 3 (13%) 2 (8%)
Age (yr), mean ± SD	28 ± 4
Weight (kg), mean ± SD	74 ± 14

Plasma TFV and FTC after encapsulation with ingestible sensor

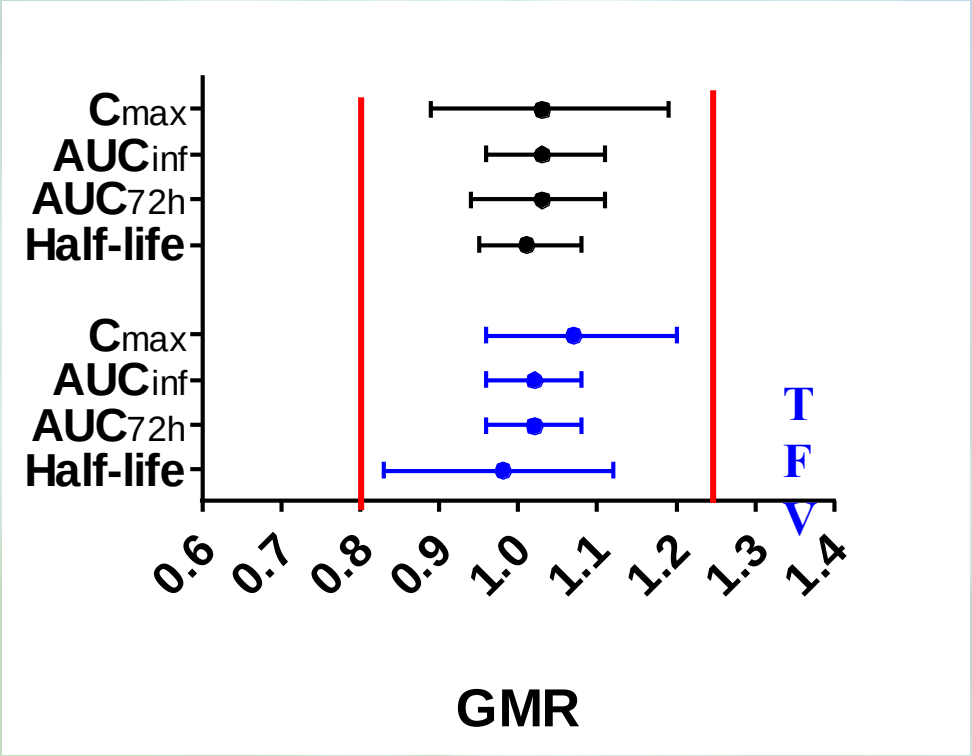
Tenofovir



Emtricitabine



Geometric Mean Ratio



Bioequivalence: GMR ratio between 80-125%

Conclusions

Bioequivalence has been confirmed for TDF/FTC co-encapsulated with the Proteus® ingestible sensor

1) Confirms medication ingestion

2) Smartphone interface that captures temporal adherence patterns

3) Real-time feedback of validated and population-specific HIV risk reduction education and health promotion

4) Use for future PrEP studies

Future Directions

- **Feasibility and Acceptability Study**
  - Cross-over study of 12 weeks dosing with and without ingestible sensor
  - Qualitatively explore acceptability
  - Adherence as measured by TFV-DP levels in DBS will be compared to adherence detected by ingestible sensor and self-report

Challenges in Digital Medicine

- Adherence to patch
- Psychological factors rather than “forgetting”
- Cost
- Privacy Concerns

Acknowledgments

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