



# **Rapid Intervention Triggered by a Pill Ingestible Sensor to Identify Non-adherence to Address Barriers from Social and Behavioral Determinants of Health for PLWH**

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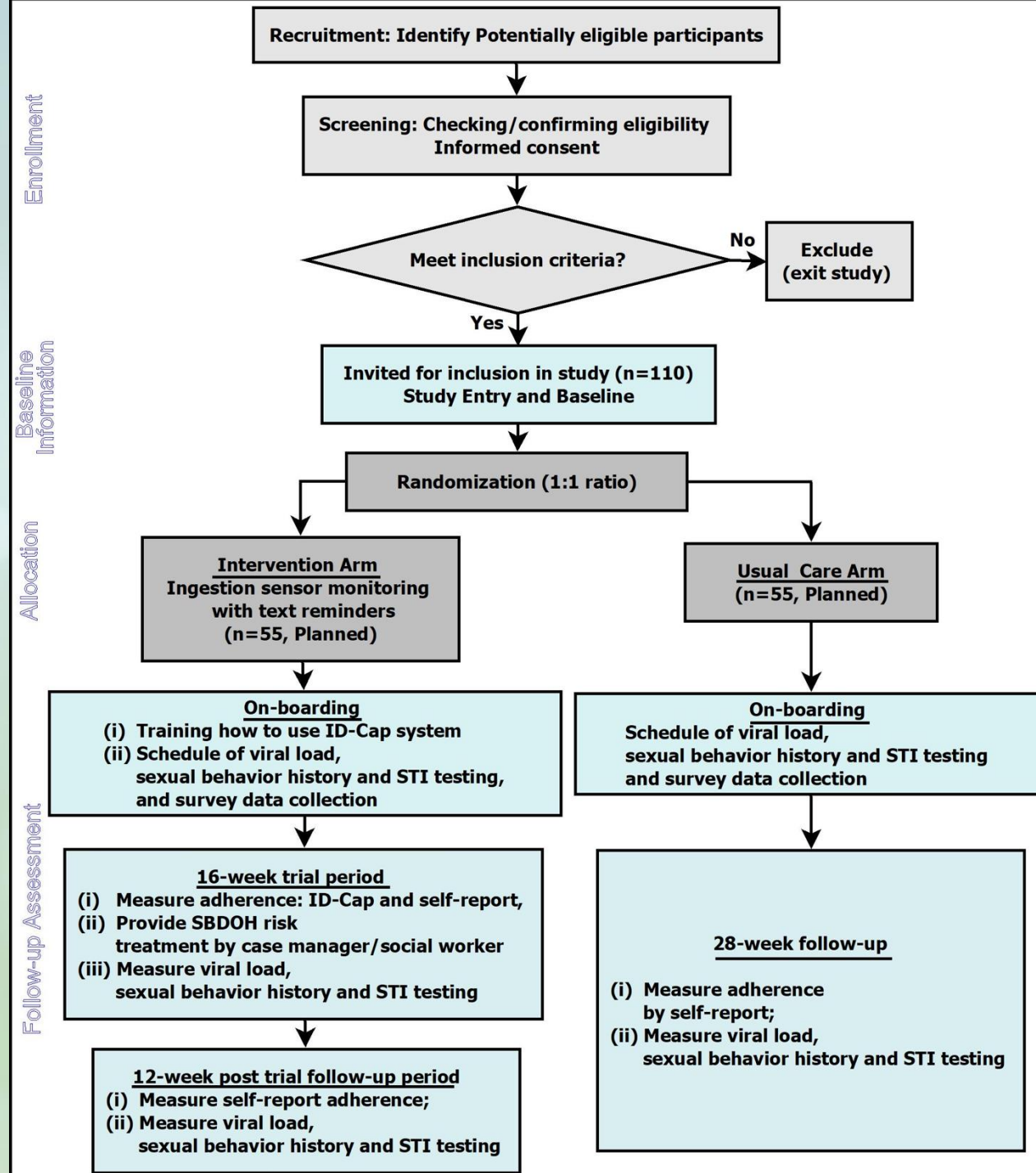
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# Overview of Trial Flow



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# Method

- **Participants were enrolled from an urban safety-net HIV clinic**
- **Inclusion criteria: People living with HIV who have poor ART adherence**
- **Randomized 1:1 to Usual care (Planned 55), or ID-Cap™ arm (Planned 55) -- (real-time ART adherence monitoring)**
- **Text reminders were sent to ID-Cap participants who missed a dose**
- **Missing 3 doses in 5 days triggered a real-time multidisciplinary team response to address SBDOH-related barriers**
- **Intervention duration: 16 weeks, followed by 12-week sustainability assessment**



# Outcomes

- **Primary outcomes:**
  - ✓ **ID-Cap-detected adherence**
  - ✓ **Self-reported adherence**
- **Secondary outcomes:**
  - ✓ **Plasma HIV RNA**
  - ✓ **CD4 count**
  - ✓ **Incidence of sexually transmitted diseases (STDs)**

# ID-Cap System

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1



## Study drug is encapsulated by the Pharmacy.

- Performed by etectRx or the Research Pharmacy.
- Delivers the study medication and reader to the site for dispensing to the participant.

2

## The patient takes the encapsulated medication.

- The ID-Capsule is activated by gastric fluid
- Transmits a digital message from the stomach
- The wearable ID-Cap Reader receives the message and forwards it to the mobile app



3

## ID-Cap App

- Reports and displays ingestion event history
- Displays reminder or confirmation messages
- Allows user to enter ingestion event manually
- Provides updates on status of Reader
- Available for iOS and Android



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## Research staff remotely monitors patient therapy using the ID-Cap Dashboard

- Real time reporting of ingestion events
- Alerts to missed events
- Automatic reminder messages to reduce missed doses
- Confirmation messages in response to ingestions
- View of individual patients or groups

4

## etectRx Servers

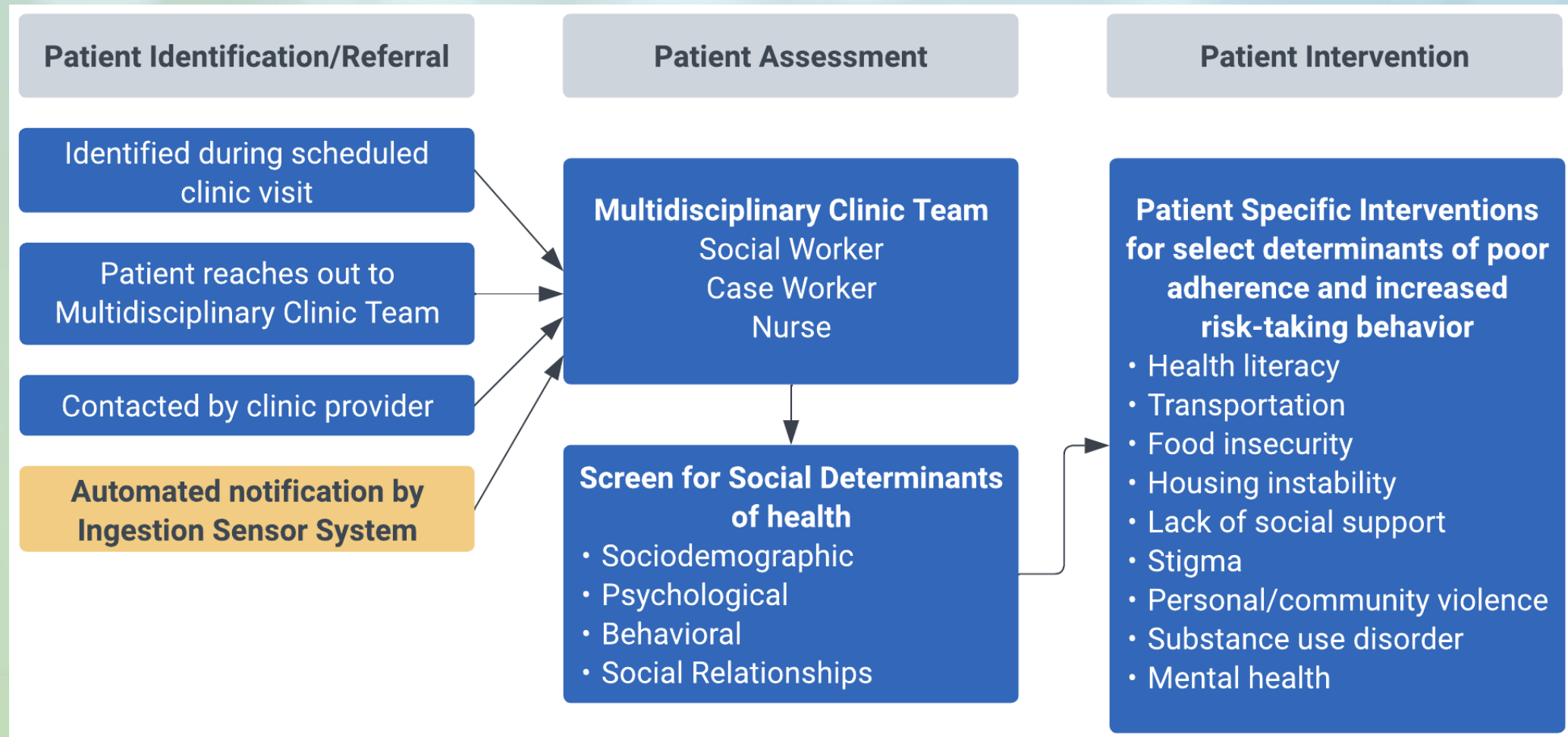
- Secure Cloud-based Storage
- Patient's Ingestion Log
- Reader status reports
- HIPPA Compliant

https  
Wi-Fi/Cellular



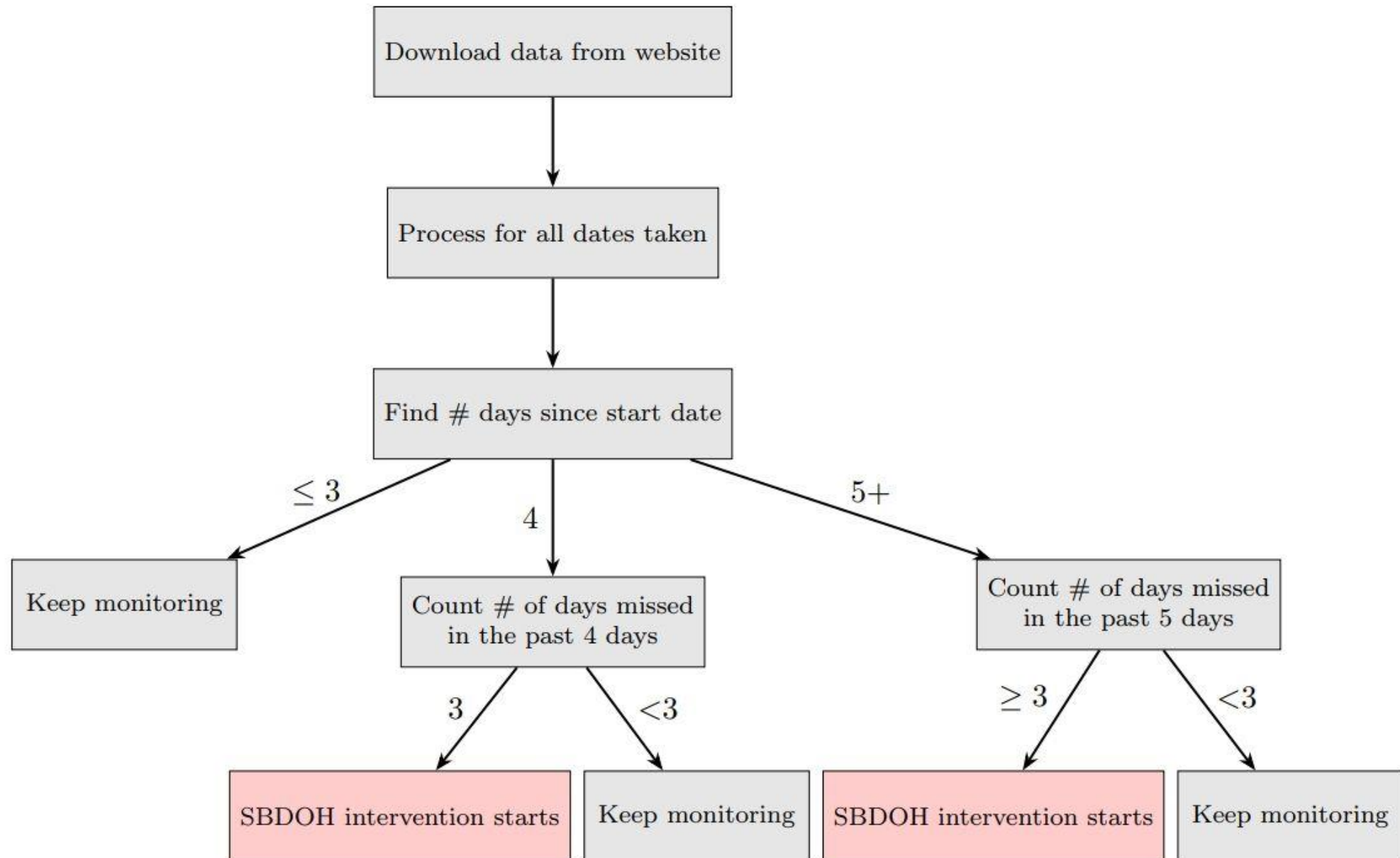
# Program For Addressing Social And Behavioral Determinants Of Health In High Risk Patients

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# When to Trigger SBDOH intervention

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# Results

- **Twenty-seven participants recruited and randomized since December 2024 (Planned 55 in each arm)**
- **Mean age: 45 years (SD 12); 95% were male**
- **Race/Ethnicity: 33% White, 48% Black, 5% Asian, 14% multiracial, 38% Hispanic**
- **76% reported substance use; 38% were viremic at enrollment**
- **Mean ID-Cap detected ART adherence: 61% (SD 32)**





# **SBD OH Intervention – What Happened When the System Was Activated**

- **Three participants triggered intervention based upon having missed 3 days over any five day period**
- **Trigger to Contact Time: All 3 patients were contacted within 7 days after the intervention was triggered**
  - ✓ **Mean contact time: 3.67 days**
  - ✓ **Range 1-7 days**
- **Comparison to Usual Care:**
  - ✓ **Under standard clinic protocol, patients are not contacted between visits (often 3–6 months apart)**



# Root Causes of Non-Adherence And Actions Taken

## Triggering participant #1:

- ✓ Reported vehicle theft with encapsulated ART medication inside
- ✓ Also reported food insecurity → Referred to food pantry

## Triggering participant #2 and #3:

- ✓ Cited etectRx reader malfunction for missed dose reporting → No social service referral made, since issue was technical rather than structural



# Lessons Learned

- Existing HIV clinic care models address SBDOH during or after missed visits—often weeks to months after adherence issues begin
- Real-time adherence monitoring enables multidisciplinary teams to promptly respond to emerging SBDOH challenges
- Tailored content can be delivered to match each individual's unique needs and barriers



# Recommendations

- **Patients' SBDOH profiles must be evaluated and incorporated with a coordinated plan to fit the patient's specific needs**
- **Interventions to address SBDOH can be conducted in a timely manner when integrated with an ingestible sensor system to avoid treatment failure**



# Conclusion

- **Rapid detection of non-adherence using an ingestible sensor system is feasible and enables a team-based approach to address SBD OH**
- **This innovative system supports timely interventions to reduce:**
  - ✓ **Risk of persistent high HIV viral load**
  - ✓ **Emergence of antiretroviral resistance**
  - ✓ **The potential for HIV transmission**



# Thank you!

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