

## Strengthening data integrity in drug trials

## >1 billion people, mainly in LMICs, do not have official forms of ID. (World Bank 2019)

Simprints' biometric identification technology enables our partners to accurately track patients and protect data integrity.

### Lack of accurate ID in drug trials can lead to...

**Cross-contamination** between test & control groups, which could make an effective intervention appear ineffective.

**Duplicate enrolments** into studies, tying multiple Case Report Forms (CRFs) to a single participant.

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Increased **Lost to Follow-up (LTFU) rates**, especially for multi-year trials.

Inability to ultimately assess a drug candidates' **side effects or effectiveness** in specific populations.

## Simprints was built for LMIC settings



We put ethics, privacy, and data security first

We are fit-for-purpose and focused on **local** capacity and community sensitivities



We are **interoperable** and integrate with the systems you already have in place



#### Simprints has two biometric modalities

A tech nonprofit building and deploying **fingerprint** and **face** biometric ID solutions for partners in LMICs.



Simprints' contact-based fingerprint solution



Simprints' contact-less face solution

# Advantages of contact-based fingerprint biometrics



## Advantages of contactless face biometrics



Reduced risk of transmission

Rapidly **deployable** 

Highly accurate data



### We plug into digital Case Report Forms



interface quides collection

Can be seamlessly integrated into existing CRF workflow

captures face or fingerprint

Mobile solution built for low-resource, 'last mile' contexts

#### matching algorithm

**Biometric identifiers** are unique, secure, and cannot be lost or forgotten

Unique ID links to records and next steps in drug trial

Offline or online. Rapid matching that reduces errors and improves accuracy and quality

#### We keep strict privacy measures

**Baseline:** adhere to strict standards

GDPR



implement privacy principles in context

**Advocacy: stronger** privacy protections



would prefer the fingerprint scanning to the SIM card scanning because the SIM card would be seen by everyone, but no one would know whose finger it is. It is private."

- woman re-initiating ART in a clinical trial in Malawi

### Simprints can be a game-changer in drug trials

#### Clinical trial outcomes with ineffective identification

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Lethabo is a part of the control group in a drug trial in Malawi.

The study she has signed up for requires her to visit the health facility 8 times over 24 months



She loses her QR code and turns up at the health clinic, but she cannot be accurately linked to her record. Instead, when searched by name, she is administered the wrong treatment.





In the absence of reliable records, **she is given the incorrect drug, undermining the data integrity for the trial.** 

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With her and many others like her going through the same process, **the study is inconclusive because of cross contamination** between the treatment and control groups.

#### Correct patient identification is a challenge because:

Beneficiaries often do not have easy ways to help health workers uniquely identify them

- Names are spelled inconsistently, and many individuals have the same name: >60% of males in a few geographies are called some variation of the same name
- Many beneficiaries do not know their exact DOB
- Slums and villages lack formal postcodes
- ID cards are frequently lost, damaged or forgotten

#### Simprints can be a game-changer in drug trials

#### Clinical trial outcomes with effective identification







Lethabo is a part of the control group in a drug trial in Malawi.

The study she has signed up for requires him to visit the health facility 8 times over 24 months.

The study utilises Simprints' fingerprint biometrics to identify her, and determine which dose / treatment she is eligible for.



She returns to health center after 10 days for a follow-up dose. When the doctor sees her, **she scans her fingerprint to pull up her unique medical record.** 



Lethabo is put on the correct treatment regimen for the test group.

Each time she returns to her local health clinic, **she is correctly identified and the correct treatment is administered.** 



When data on the effectiveness of the drug is analysed, biometrics helps ensure integrity of data quality.

# Case study: Improving HIV outcomes in women

BROWN





#### Case study: Evaluating HIV/TB treatment methods

\*DETAILS CONFIDENTIAL - UNDER EMBARGO, SUBMITTED FOR PUBLICATION Researchers at an East African institution used Simprints to track 12,870 patients in TB/HIV care across clinics to monitor control and intervention arms to improve TB/HIV care.

Outcome 1 No 'contamination' between intervention & control groups, which "is unprecedented".

Outcome 2

Enabling individual-level data has allowed for the first time to correlate HIV and TB data to specific risk factors.

#### Simprints' value-add at a glance

ID system helps **eliminate cross-contamination** between test and control groups, which can otherwise make an effective intervention appear ineffective.

For multi-country, multi-site, and/or multi-follow ups trials, unique ID ensures data integrity, **especially important for new vaccines like Covax.** 

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When continuity of care relies on robust ID methods, biometrics can **minimise Lost to Follow-up (LTFU) rates.** 

Biometrics offers **stronger privacy protection** for participants than other ID methods do, encouraging sign-ups.

# THANK YOU

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