Clinical Trials Hub

MATRIX: A USAID Project to Advance the Research and Development of Innovative HIV Prevention Products for Women

Luis Duran & Ingrid Macio

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PEPFAR

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FROM THE AMERICAN PEOPLE

MATRIX
Advancing R&D of Innovative
HIV Prevention Products for Women

Clinical Trials Hub

Executive Director and Co-Lead Clinical Trials Hub
Sharon Hillier, PhD
UPitt, MWRI, USA

Co-Lead Clinical Trials Hub
Nyaradzo Mgodi, MBChB, MMed
HHRC, Zimbabwe

CTH Clinical Research Manager
Ingrid Macio, PA-C
MWRI, USA

CTH Safety Physician
Katherine Bunge, MD, MPH
UPitt, MWRI, USA

CTH Support
Luis Duran, DrPH
MWRI, USA

CTH Management & Statistical Support
Leslie Meyn, PhD
UPitt, MWRI, USA

CTH Lab Support
May Beamer, BS
MWRI, USA

CTH Clinical Research Support
Jamie Haggerty, BA
MWRI, USA

CTH Safety Physician
Catherine Chappell, MD, MSc
UPitt, MWRI, USA

CTH Support
Mei Song, PhD
MWRI, USA

CTH Management & Statistical Support
Tracy Zamborsky, MBA
MWRI, USA

CTH Lab Support
Ted Livant, BSMT (ASCP), MPH
MWRI, USA

CTH Support
Michelle Leszczewski, BA
MWRI, USA

CTH Management & Statistical Support
David Crowe, BA
MWRI, USA

Consultant Pharmacy:
Cindy Jacobson, PharmD

Independent Safety Physician:
Sharon Riddler, MD

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What are we doing? Our CTH Year 2 Workplan

- 3.04: Support conduct of CONRAD Phase I safety/PK study (MATRIX-001)
- 3.05: Support conduct of Pitt placebo study (MATRIX-002)
- 3.06: Support conduct of Oak Crest placebo study (MATRIX-003)
- 3.07: Update Clinical Trial Capacity Catalog of SSA sites
- 3.08: Create and maintain Clinical Trial Status Update Table
- 3.09: Develop Protocol Concept template
- 3.10: Establish Procedures for Protocol Chair/Co-Chair Selection
- 3.56: Establish Procedures for Study Activation oversight
- 3.57: Establish Procedures for Laboratory oversight
- 3.58: Develop Laboratory Capacity Catalog of SSA sites

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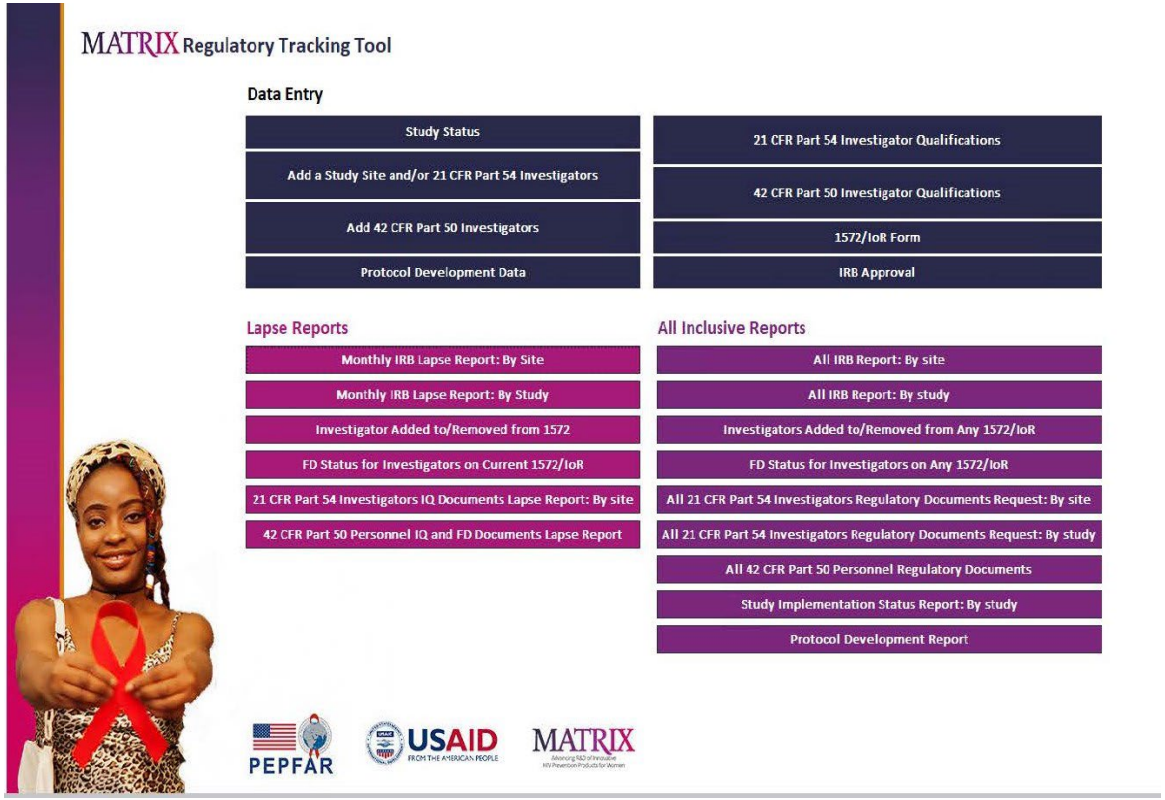
The first 3 protocols

Luis Duran, DrPH

- MATRIX-001: TAF EVG insert (CONRAD). Version 1
  - **Three** sites will do the study
    - EVMS (US), CAPRISA-eThekwini (South Africa) and KEMRI (Kenya)
- MATRIX-002: Placebo Film study (Pitt). Version 1
  - **Five** sites will do the study
    - Pittsburgh (US), Aurum-Klerksdorp (South Africa), HHRC (Zimbabwe), KEMRI (Kenya) and Wits RHI (South Africa)
- MATRIX-003: Placebo IVR study (Oak Crest). Version 1
  - **Five** sites will do the study
    - Pittsburgh (US), Aurum-Tembisa (South Africa), CAPRISA-Vulindlela (South Africa), HHRC (Zimbabwe) and Wits RHI (South Africa)

Regulatory Tracking Tool

David Crowe, BA



In-house tracking tool to assist MATRIX Regulatory staff with

- Monitoring protocol development and study implementation milestones, including IRB/IEC approvals and renewals
- Monitoring investigator qualification and financial disclosure documentation of site investigators and non-site personnel

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Regulatory Tracking Process

Mei Song, PhD

- What data do we enter?
  - Protocol development milestone dates (e.g., USAID submission and approvals)
  - Study/site implementation milestone dates (e.g., site trainings, accrual start, etc.)
  - Investigator qualification documentation (i.e., CV, HSP, GCP, clinical licenses)
  - Financial disclosure documentation (i.e., MATRIX-wide, study-specific)
  - Site IRB/IEC/DRA approval and renewal dates
  - Form FDA 1572 or MATRIX IoR Form dates and site staff listed
- How do we process and track data?
  - Save copies of selected essential documents from sites on secured R drive
  - Enter dates in the internal Regulatory Tracking Tool followed by weekly quality check
  - Generate IQ, IRB and FD lapse report monthly
  - Request sites to send needed documents monthly

Study Activation Process

Ingrid Macio, PA-C

Jamie Haggerty, BA

- Provide/review protocol specific supporting documents and/or templates to ensure consistency between MATRIX studies and sites, including but not limited to:
  - Study specific procedure (SSP) Manual
  - Delegation of Duties Log
  - Screen/Enrollment Log
  - Informed Consent Coversheet
  - Informed Comprehension Assessment
  - Counseling Guide and Worksheet
  - PSRT Query Form
  - Visit Checklists
- In collaboration with ACRO and PD reps, CTH/CRM coordinates completion of items on sites' Study Activation Checklists

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Study Specific Procedure (SSP) Manual

- For MATRIX-001, draft development coordinated by CONRAD
  - Templates provided by CTH/CRM, with multiple rounds of iterative input and review from CTH, D2D Pillar 2, and other Management Team members
- For MATRIX-002 and MATRIX-003, draft development coordinated by CTH/CRM
  - Templates also provided by CTH/CRM, with multiple rounds of iterative input and review from PD, CTH, D2D Pillar 2, and other Management Team members

Laboratory

Ted Livant, BSMT, MS, ASCP

May Beamer, BS

- Pre-study laboratory approval process requirements will vary between USA/CLIA and SSA sites
- Separate lab activation checklist to be implemented, i.e., External Quality Assurance, Qualifications, Method Validations, Standard Operating Procedures
- Site laboratory oversight
  - Specimen and testing menus established for MATRIX-001 and MATRIX-002
  - Specifications obtained for higher complexity samples
  - Lab capacity questionnaires sent to Kenya and South Africa sites
  - Nyaradzo Mgodi Kenya visit scheduled for mid-August 2023
  - Developed QC system for tracking of samples in LDMS
  - Laboratory SSP sections, including PK biopsy collection steps for MATRIX-001
  - Shipping Considerations-Material Transfer Agreements

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Data Management

Leslie Meyn, PhD

Tracy Zamborsky, MBA

- For MATRIX-002 and MATRIX-003, data will be collected and housed in a REDCap Database at the Clinical and Translational Science Institute at the University of Pittsburgh
- Preparation for Database Set up and Design
  - Create Case Report Forms
  - Implement CRFs in user-friendly digital format for direct data entry
  - Build database for longitudinal data collection
  - Set up Data Access Groups
  - Test and validate
- Preparation for site activation
  - Train staff on navigating REDCap Dashboard, form flow, and form completion
  - Set up user accounts, put into appropriate DAGs, and manage user rights
  - Work as liaison between staff and REDCap Administrator as needed

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Site Monitoring

acro
african clinical research organisation
transforming ideas into solutions

Ensure your venture blossoms in Africa.

There's no harm in a little local help.

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Company Overview

- ACRO (African Clinical Research Organisation) was the first South African, full-service, black economic empowerment, contract research organisation (CRO)
- We offer services both in Southern Africa and in other African regions
- ACRO is a private company, launched in August 2007

What do we offer?

- We offer services to:
  - Donor-funded organisations
  - Non-governmental organisations
  - Government institutions
  - Research institutions
  - Academic institutions
  - Pharmaceutical companies
  - Medical device companies, and
  - Work both within and outside the biotechnology sector

We are African
We know Africa
We live Africa
We love Africa

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Our Services

- ACRO provides a full-service offering for Phase I – IV trials
- ACRO is organised into five departments:
  - Clinical Trial Management and Monitoring
  - Regulatory and Medical Affairs
  - Data Management Services
  - Training: Accredited GCP, Clinical, Data Management, Ethics and customised courses
  - Clinical Trial Site Development (including site identification, establishment of site administrative and physical infrastructure, and GCP training of site staff)
- These departments work together to ensure our clients receive an integrated service that is tailored to their unique needs.

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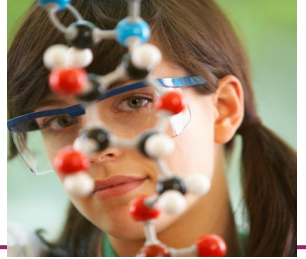
Our Team



- The ACRO team has:
  - >40 years cumulative multinational clinical trial experience
  - in South Africa and the Rest of Africa
  - across therapeutic indications, and
  - in conducting pivotal, non-pivotal, IND and non-IND studies
  - in accordance with international and local regulatory requirements
- Our medium-sized infrastructure and experience is comparable to that of larger, more experienced CROs.

Types of Monitoring Visits

- Pre-Study Visit (PSV)
- Site Initiation Visit (SIV)
- Interim Monitoring Visits (IMV)
- Site Close Out Visit (SCV)

MATRIX-001 Start-up Status

- Submission made to the South African Health Products Regulatory Authority (SAHPRA) on 07 July 2023, with Clinical Trial Committee (CTC) Review Meetings completed on 03 & 04 August 2023, and final approval expected in August 2023
- Submission made in parallel to the Research Ethics Committee (REC) in June 2023, in accordance with their submission timelines
- SAHPRA and REC approvals are expected to be completed no later than August/September 2023
- RA and REC approvals for Kenya are expected to be completed within 3 - 6 months of submission to their respective RA-RECs and no later than October 2023

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MATRIX-002 Start-up Status

- Submission made to the SAHPRA on 11 August 2023, with CTC Review Meetings scheduled for 07 & 08 September 2023, and final approval expected in September/October 2023
- Submission made in parallel to the RECs in August 2023, in accordance with their submission timelines
- SAHPRA and REC approvals are expected to be completed no later than September/October 2023
- RA and REC approvals for Kenya and Zimbabwe are expected to be completed within 3 - 6 months of submission to their respective RA-RECs and no later than October 2023

MATRIX-003 Start-up Status

- Submission will be made to the SAHPRA on or before 20 October 2023, with CTC Review Meetings scheduled for 16 & 17 November 2023, and final approval expected in December 2023
- Submission will be made in parallel to the RECs in October 2023, in accordance with their submission timelines
- SAHPRA and REC approvals are expected to be completed no later than December 2023
- RA and REC approvals for Zimbabwe are expected to be completed within 3 - 6 months of submission to their respective RA-RECs and no later than December 2023/January 2024

CTH Summary and Next Steps

- The Clinical Trials Hub was developed to support the development and implementation of phase 0 and 1 trials in support of MATRIX products.
- We are here to support product developers and the clinical trial sites to ensure that the studies are conducted at high standards.
- New study concepts for the next round of trials are being discussed with PDs and we hope to develop three more protocols in 2024.

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Acknowledgements

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The contents in this presentation are those of the presenter and do not necessarily reflect the view of the U.S. President's Emergency Plan for AIDS Relief, the U.S. Agency for International Development or the U.S. Government.