CHWs as clinical trial staff: strategies used and lessons learned from a study in rural Uganda

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Collaborators

Co-Authors

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- Anja Lendvay
- Brian Perry
- Anthony Mbonye, MD, PhD

Organizations

USAID FROM THE AMERICAN PEOPLE

PROGRESS IN FAMILY PLANNING

The Republic of Uganda

PATH

Outline

1. Overview of the study
2. CHW Qualifications
3. Recruitment and Informed Consent
4. Documentation
5. Study Product
6. Oversight

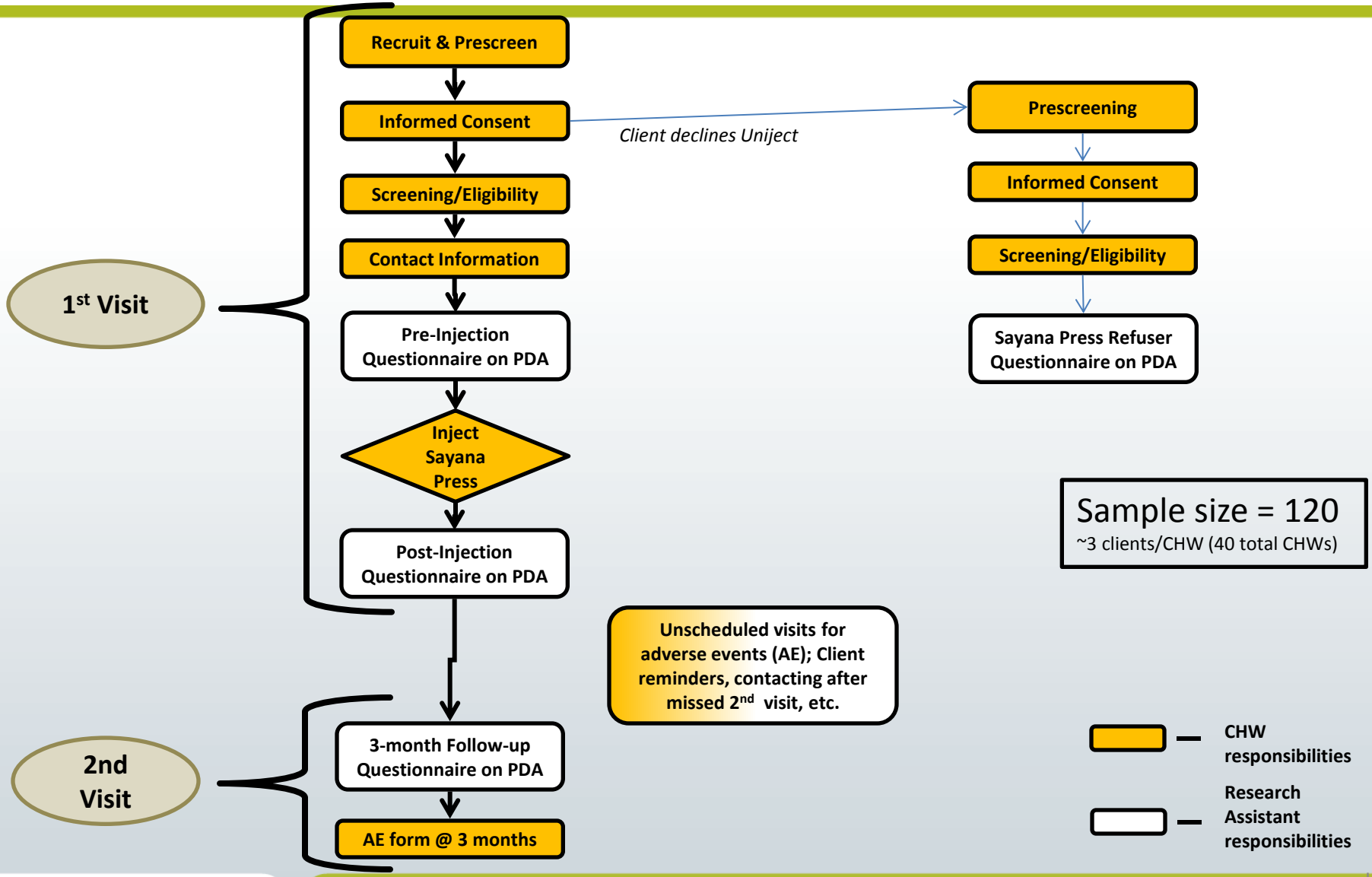
Research Objectives

1. Measure the acceptability of Sayana Press among DMPA IM family planning **clients** (N=120)

2. Measure the acceptability of Sayana Press among family planning **providers** (N=40 community health workers [CHWs])
   - Timeline: 6 months for data collection

Acceptability Study of Depo-subQ in Uniject - Uganda:

CHW Responsibilities

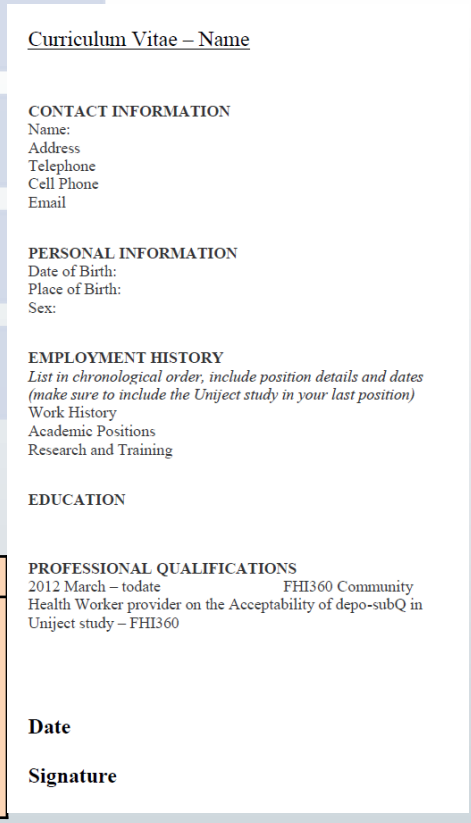


Qualifications: GCP Principle

- **2.8** Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s).

Qualifications

Pre-requisite	• How it was determined
Authorized to provide family planning in their country;	•Study obtained from MOH prior to invitation to join
At least six months of experience of counseling and providing family planning methods to clients;	•CV (with study support)
Literate in their own language (Luganda);	•CV (with study support)
Trained to provide Sayana Press for the purpose of this study;	•Study provided (PATH conducted)
Trained in Good Clinical Practice (GCP), human research ethics, and the study protocol.	•Study provided



Curriculum Vitae – Name

CONTACT INFORMATION
Name:
Address
Telephone
Cell Phone
Email

PERSONAL INFORMATION
Date of Birth:
Place of Birth:
Sex:

EMPLOYMENT HISTORY
List in chronological order, include position details and dates (make sure to include the Uniject study in your last position)
Work History
Academic Positions
Research and Training

EDUCATION

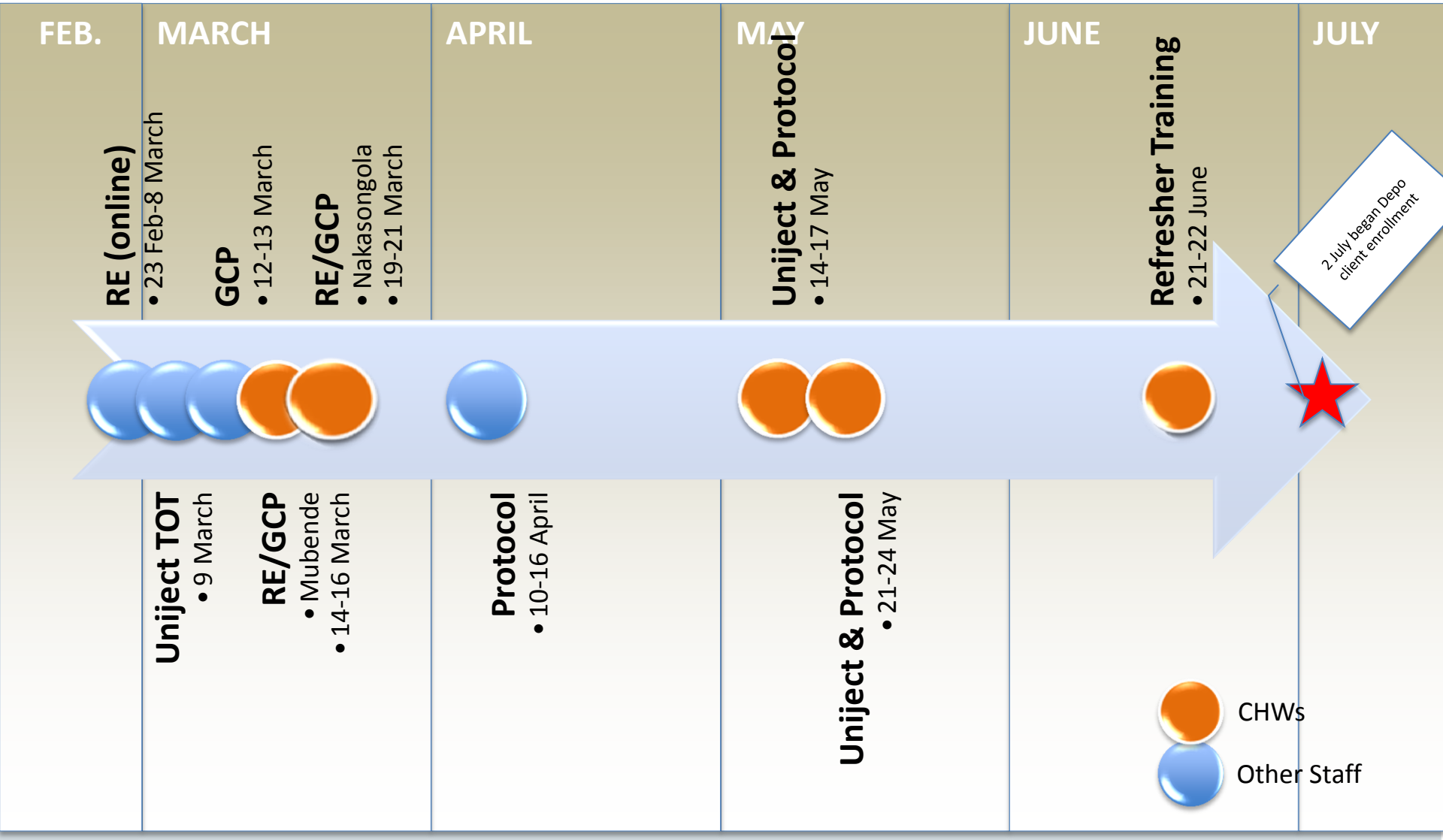
PROFESSIONAL QUALIFICATIONS
2012 March – todate FHI360 Community Health Worker provider on the Acceptability of depo-subQ in Uniject study – FHI360

Date

Signature

GCP Essential Document		
8.2.10	CURRICULUM VITAE AND/OR OTHER RELEVANT DOCUMENTS EVIDENCING QUALIFICATIONS OF INVESTIGATOR(S) AND SUB-INVESTIGATOR(S)	To document qualifications and eligibility to conduct trial and/or provide medical supervision of subjects

UGANDA TRAINING TIMELINE: 2012



Recruitment and Informed Consent: GCP Principles

- **2.9** Freely given informed consent should be obtained from every subject prior to clinical trial participation.
- Recruitment procedures and any written information to be given to the subject must be reviewed and approved by and IRB.

GCP Essential Document		
8.2.3	**INFORMATION GIVEN TO TRIAL SUBJECT**	
	- INFORMED CONSENT FORM (including all applicable translations)	To document the informed consent
	- ANY OTHER WRITTEN INFORMATION	To document that subjects will be given appropriate written information (content and wording) to support their ability to give fully informed consent
	- ADVERTISEMENT FOR SUBJECT RECRUITMENT (if used)	To document that recruitment measures are appropriate and not coercive

Recruitment

- Approved recruitment process: No community recruitment. When client arrives for normal visit, CHW has a simple "script" to introduce the study
  - Hello! My name is _____and I am a Family Planning Provider with the Ministry of Health. We are doing research to learn more about the acceptability of a family planning method. The results of this study will aid in improving the provision of family planning in this community. This study will include women in general good health, who are at least 18 years of age, have been using DMPA continuously without a break for at least six months and want to continue using DMPA. Are you interested in finding out more about being a participant in this research?
  - Issue:
    - When setting up an appointment with a client, how to prepare clients for a potentially longer visit without discussing the study?
    - How to ask a client to meet with a different CHW to help with recruitment
- Protocol Amendment Suggestion: Revised to "guidance"
  - Allow study introduction over the phone
  - Conduct greetings and introduction as normally done with client. When ready to speak about the study, give the following type of information: (see script above). You may provide the client information needed to make the appointment. For example:
    - Length of the enrollment visit
    - Other study staff who may be at the appointment or who may contact client to schedule visit
    - She will be free to leave the visit at any time
    - Delay providing details about the study and study product until you have time to do the informed consent process.

Informed Consent

Conducted by a Research Assistant or CHW? Competing GCP (and ethical) principles considered:

- 4.8.3 Neither the investigator, nor the trial staff, should coerce or unduly influence a subject to participate or to continue to participate in a trial.
  - Concern about undue influence mitigated by
    - No community recruitment; all clients returning for DMPA re-injection
    - No compensation to clients or CHWs for enrollment
- 4.8.5 …should fully inform the subject … of all pertinent aspects of the trial. And 4.8.7 should provide the subject … ample time and opportunity to inquire about details of the trial …. All questions about the trial should be answered to the satisfaction of the subject.
  - CHWs have the most knowledge about Sayana Press and DMPA to be able to answer medical questions;
  - CHW training on research ethics, GCP and the study would be comparable to Research Assistants

Process Support

- IC Comprehension Assessment Tool

Confidentiality

- Done in the community (home, market, etc.); CHWs very familiar with confidentiality due to secret use of injectable contraceptive, though this was a longer visit

Document Integrity and Security: GCP Principles

- **2.10** All clinical trial information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification.
- **2.11** The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s).

Document Storage: Location

Document Storage

- Secure storage of files and timely transport
  - Stored at clinic in locked file cabinet
    - 5 clinics chosen based on proximity to CHWs and facility capacity for study needs
    - Research Assistants deliver participant files to CHW for ***scheduled*** appointments.
    - Medical Coordinator transported participant files for ***unscheduled*** appointments. Files stored with study product while with the CHW.
  - Stored at CHW home in locking cabinet
    - CHWs returned to clinic when picking up or dropping off study product

Document Storage (continued)

- Copier
  - To make available all documents
  - For source documents - copied when CHWs dropped off documents; required that client participant ok with CHW taking the source document (e.g. FP card)

Power source needed

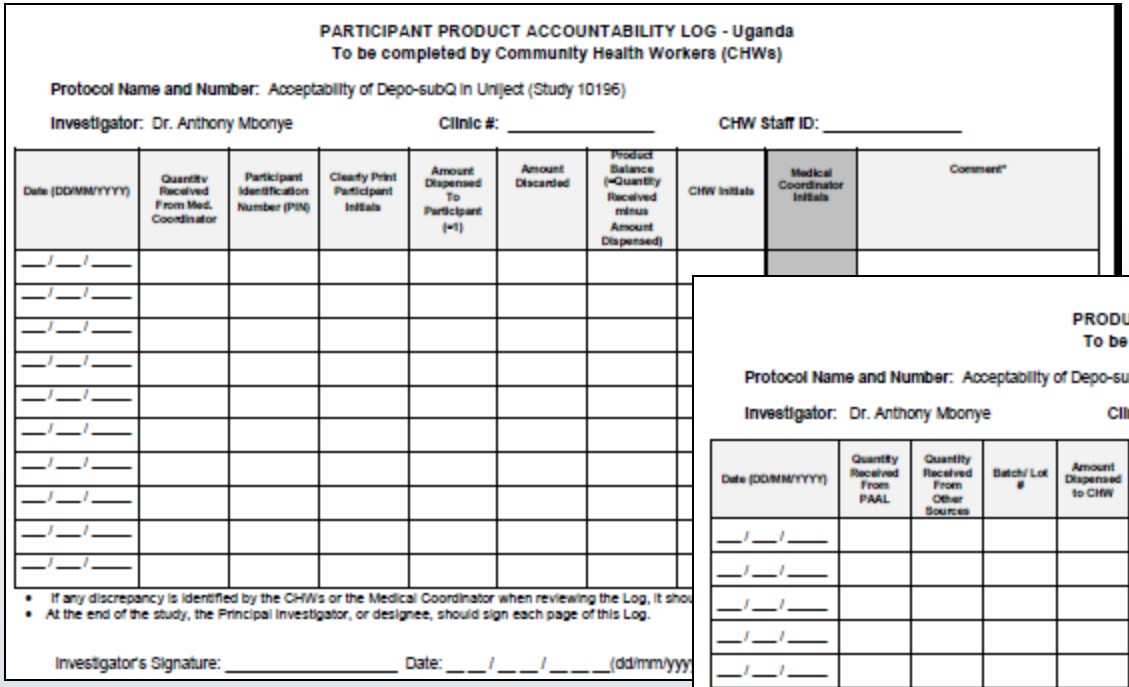
Security for copier equipment required

Study Product

- **2.12** Investigational products should be manufactured, handled, and stored in accordance with applicable good manufacturing practice (GMP). They should be used in accordance with the approved protocol.

Study Product Accountability

- Log for both central storage (by Medical Coordinator) and community (by CHW).
- **Community storage limited to M-F only.**



PARTICIPANT PRODUCT ACCOUNTABILITY LOG - Uganda
To be completed by Community Health Workers (CHWs)

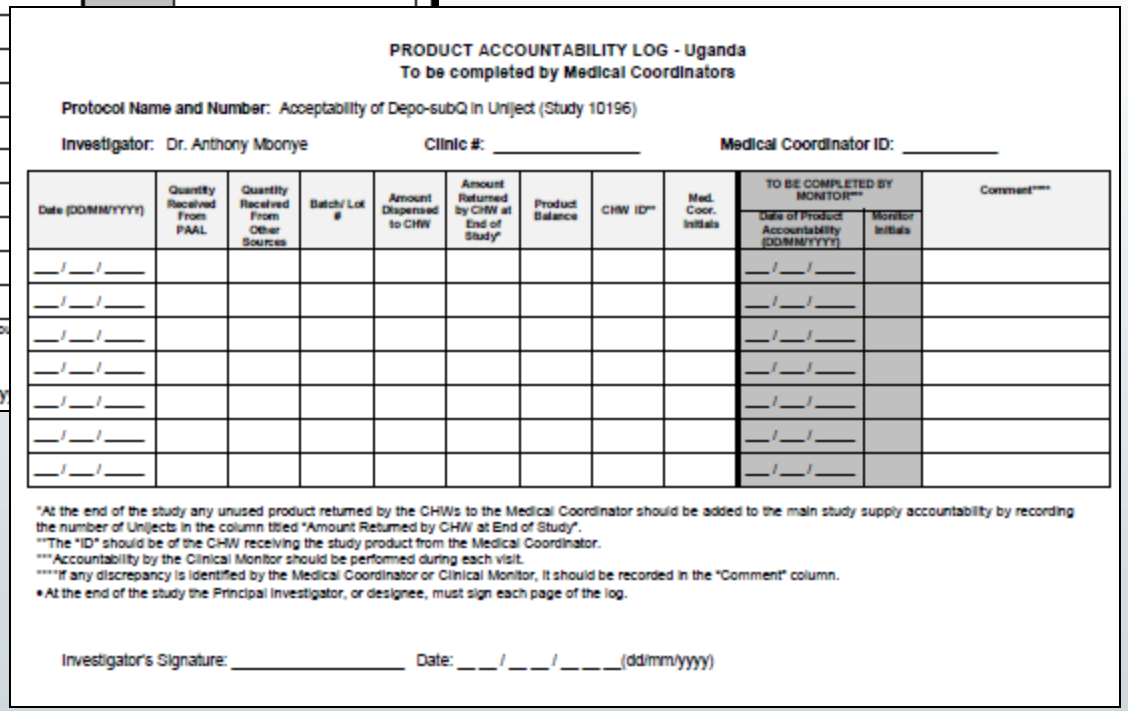
Protocol Name and Number: Acceptability of Depo-subQ in Uniject (Study 10196)

Investigator: Dr. Anthony Mbonye **Clinic #:** _____ **CHW Staff ID:** _____

Date (DD/MM/YYYY)	Quantity Received From Med. Coordinator	Participant Identification Number (PIN)	Clearly Print Participant Initials	Amount Dispensed To Participant (=1)	Amount Discarded	Product Balance (=Quantity Received minus Amount Dispensed)	CHW Initials	Medical Coordinator Initials	Comment*
__/__/____									
__/__/____									
__/__/____									
__/__/____									
__/__/____									
__/__/____									
__/__/____									
__/__/____									
__/__/____									
__/__/____									

- If any discrepancy is identified by the CHWs or the Medical Coordinator when reviewing the Log, it sho
- At the end of the study, the Principal Investigator, or designee, should sign each page of this Log.

Investigator's Signature: _____ Date: __ __/__ __/__ __ __ __(dd/mm/yyy



PRODUCT ACCOUNTABILITY LOG - Uganda
To be completed by Medical Coordinators

Protocol Name and Number: Acceptability of Depo-subQ in Uniject (Study 10196)

Investigator: Dr. Anthony Mbonye **Clinic #:** _____ **Medical Coordinator ID:** _____

Date (DD/MM/YYYY)	Quantity Received From PAAL	Quantity Received From Other Sources	Batch/ Lot #	Amount Dispensed to CHW	Amount Returned by CHW at End of Study*	Product Balance	CHW ID**	Med. Coor. Initials	TO BE COMPLETED BY MONITOR***		Comment****
									Date of Product Accountability (DD/MM/YYYY)	Monitor Initials	
__/__/____									__/__/____		
__/__/____									__/__/____		
__/__/____									__/__/____		
__/__/____									__/__/____		
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*At the end of the study any unused product returned by the CHWs to the Medical Coordinator should be added to the main study supply accountability by recording the number of Unijects in the column titled "Amount Returned by CHW at End of Study".
**The "ID" should be of the CHW receiving the study product from the Medical Coordinator.
***Accountability by the Clinical Monitor should be performed during each visit.
****If any discrepancy is identified by the Medical Coordinator or Clinical Monitor, it should be recorded in the "Comment" column.
• At the end of the study the Principal Investigator, or designee, must sign each page of the log.

Investigator's Signature: _____ Date: __ __/__ __/__ __ __ __(dd/mm/yyyy)

Study Product Storage

Shelves built to store product correctly at the clinic

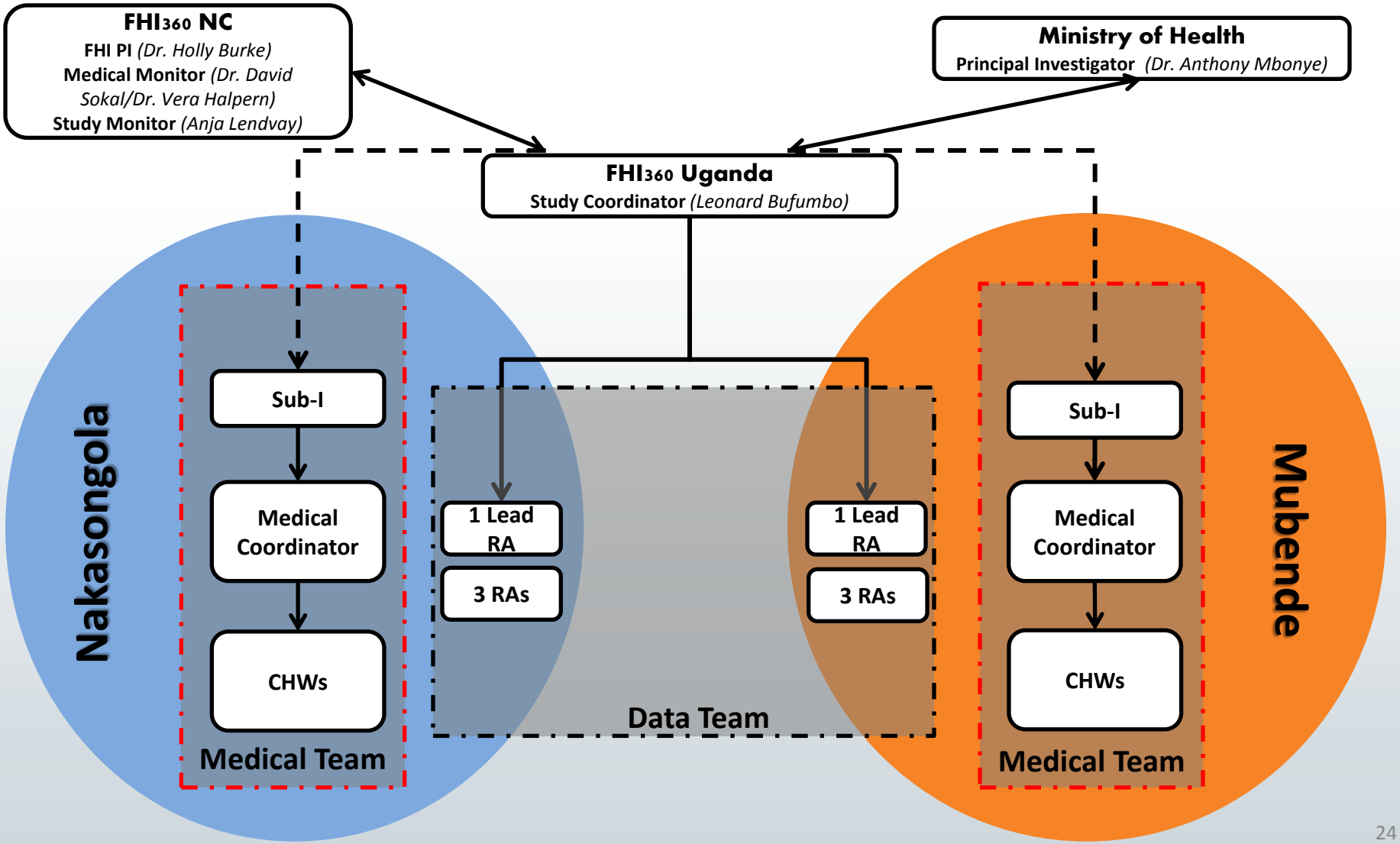
CHW's locking cabinet at home
(provided by CBD program, not study)

Oversight: GCP Principles

- **2.7** The medical care given to, and medical decisions made on behalf of, subjects should always be the responsibility of a qualified physician or, when appropriate, of a qualified dentist.

- **2.13** Systems with procedures that assure the quality of every aspect of the trial should be implemented.

Acceptability Study of Depo-subQ in Uniject: Uganda Staff Organization



Oversight

- 1st injection given observed and supported by the Medical Coordinator.
- CHW informs the Medical Coordinator of any potential adverse events. Medical Coordinator and sub-Investigator follow-up to support medical needs and to ensure that all serious adverse events (SAEs) are captured and documented.
- Study Coordinator visits approximately every other week.
- FHI 360 NC Monitoring/Quality Assurance visits: start up, middle, close out

Protocol Violations = 35

# of occurrences	Description	Resolution
1	Other Medical coordinator (MC) administered Sayana Press injection when CHW was too nervous to administer the injection	Trained MC on proper procedures if this arises in the future (i.e., do not enroll pt and administer depo IM injection instead)
2	Ineligible participant enrolled	Retrained CHW on proper age range
3	An RA/MC initialed CRF on behalf of a CHW	Retrained site staff and CHWs that they should never sign any study document on behalf of someone else.
3	IC destroyed after error identified; new IC created	Retrained site staff
26	Participant enrolled > 13.0 weeks after last injection	Retrained site staff and remaining CHWs on proper criterion of number of weeks since last injection no more than 13 weeks 0 days; amended protocol to 15 weeks 0 days.

Conclusions and Lessons Learned

- CHWs can participate as staff in clinical trials with reasonable measures instituted
- Time to develop processes and tools to support CHWs is essential
  - This requires the close collaboration of the research team and program staff familiar with CHW day-to-day work flow
- Supervision is necessary, signs of appreciation are invaluable

Thank You

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