

# IMPLEMENTATION OF VOICE IN A MULTI-SITE CTU LESSONS LEARNT AND FUTURE INSIGHTS

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**ON BEHALF OF THE MRC CTU  
HIV PREVENTION RESEARCH UNIT**

**MTN REGIONAL MEETING  
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South African Medical Research Council

BUILDING A HEALTHY NATION THROUGH RESEARCH

# MTN003 TURNS 1

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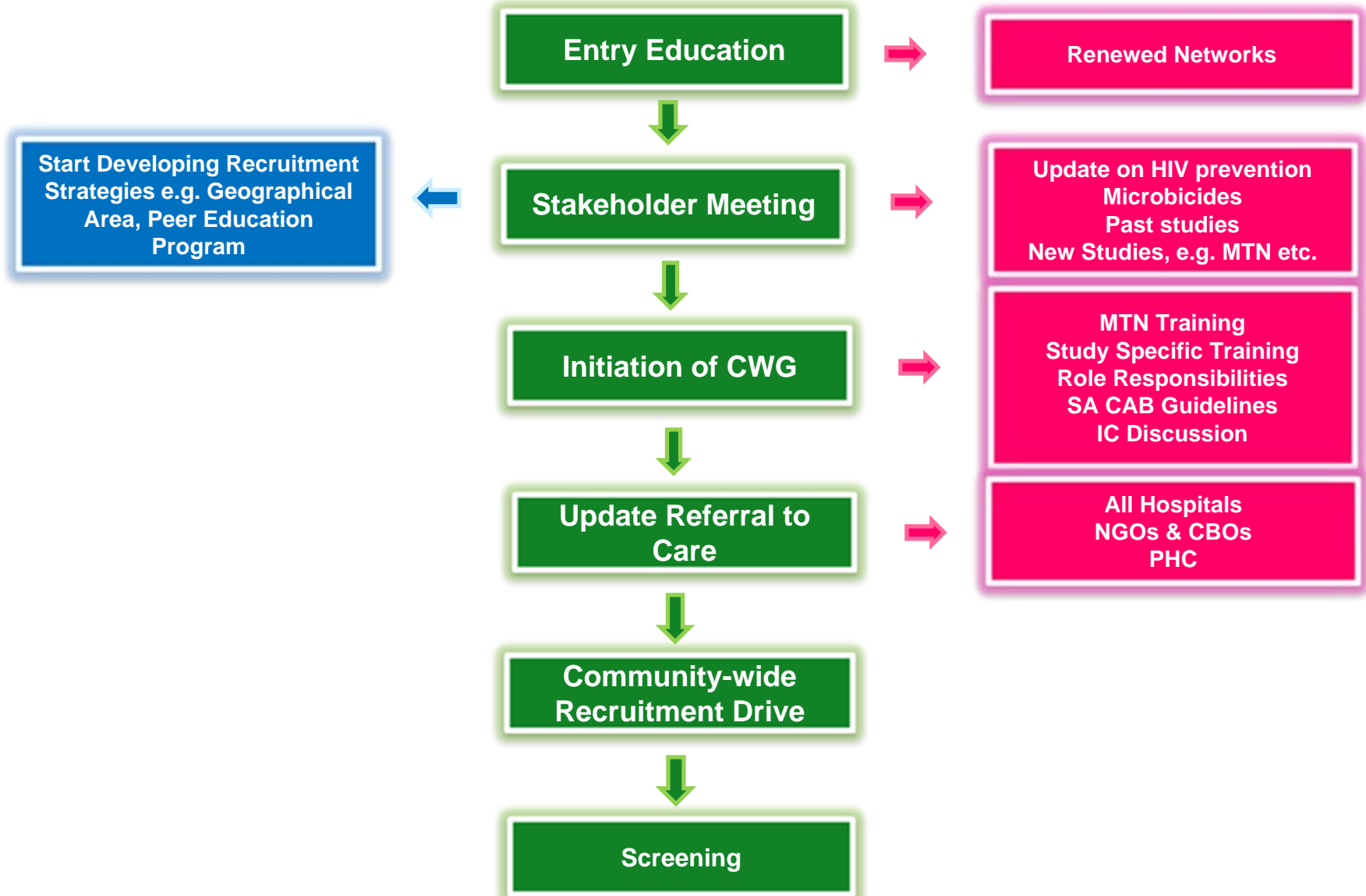


ARE YOU  
**PrePARED**  
FOR HER TO  
**VOICE**  
HER FIRST WORDS?

- **Community Entry**
- **VOICE Clinical Trial Sites**
- **Current Update**
- **Accrual Challenges**
- **Strategies Implemented**
- **Communication Challenges**
- **Courier Specimen Collection**
- **Communication in a Multi site CTU**
- **Quality Management of VOICE**
- **Lessons Learnt**
- **Future Insights**

# COMMUNITY ENTRY

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# HPRU VOICE CLINICAL TRIAL SITES

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- BOTHA'S HILL
- CHATSWORTH
- ISIPINGO
- OVERPORT
- TONGAAT
- UMKOMAAS
- VERULAM

# CURRENT UPDATE

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Site	Screened	Enrolled	HIV Prevalence	Retention Rate %
Botha's Hill	516	148	26	93
Chatsworth	471	147	14	100
Isipingo	427	153	17	100
Overport	460	87	36	84
Tongaat	564	148	34	96
Umkomaas	364	122	24	95
Verulam	538	136	28	94

\* Status as of 27 August 2010 MTN003 Screening and Enrollment Report except Retention Rate which is from Project Status Log 01 October 2010

## Education of VOICE

- Novel concept
- Lack of understanding ARVs for prevention
- Fear of HIV testing (stigma)
- Fear of side effects
- Fear of resistance
- CAP 004 results impact

## Strategies

- Intense community education drive use tools available through: MTN and local
- Constant and consistent
- Extensive discussion with community and political leaders
- Engaging men
- Education session provided in waiting area by nurses, clinicians and pharmacists

- **Stringent eligibility criteria**
- **Delayed access to referrals/ care**
- **Long duration of study visits**
- **Strict regular safety monitoring**
- **Implementation of multiple sub studies 015/016/009**
- **Running these studies concurrently with VOICE**
- **Highly mobile population (effect on retention)**
- **Recruitment and training of new staff**



## Recruitment /Retention

- Weekend Clinics
- Letter to Employers
- Providing Transport
- Telephone Reminders
- Core-talk – sms reminder, Birthdays
- TV, DVD, Entertainment & Provision of Snacks
- Tracking Database

## Adherence

- Multi-disciplinary Approach & Different Groups, e.g. Waiting Rooms, Counselors, Nurses, Clinicians & Pharmacists

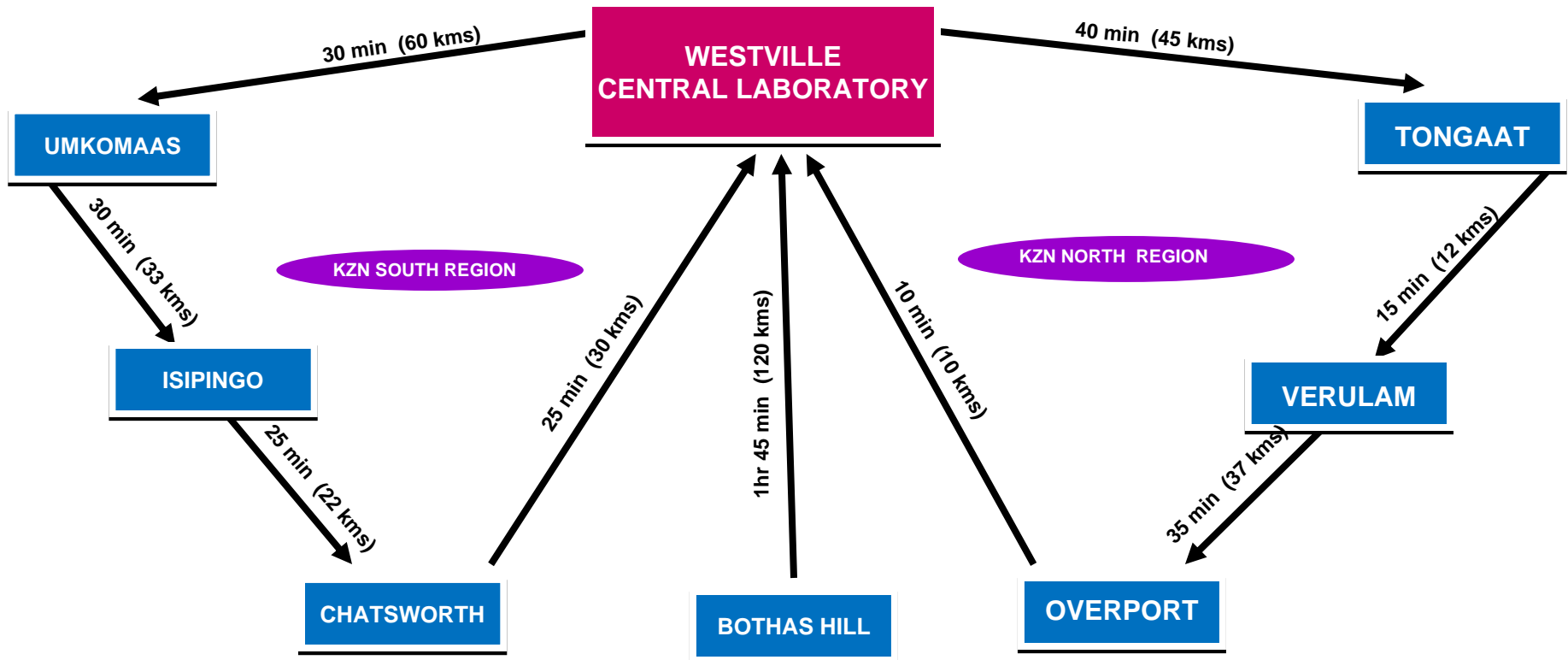
## Access to Care

- Referral Letter
- Point of Care
- MOU with Local Clinics/Hospitals

- **As a multi-centered CTU effective communication is a key ingredient to trial and protocol implementation**
- **Concurrent MTN sub-studies weigh heavily on sites**
- **In order to successfully merge the various protocols at the seven sites, effective lines of communication are essential to ensure consistency and quality of our data**
- **It is for this reason that precedence has been given to the MTN weekly meeting and the creation of a clinical trial E-group**
- **It provides a platform to discuss challenges, identify trends and clarify issues across sites**
- **The success of this approach has only worked due to perseverance and team spirit**

# COURIER– SPECIMEN COLLECTION

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Travel time for KZN South Region 2 hours 30

Specimen in transit after first collection 2 hours

Two Trips – 12H 00  
16H 30

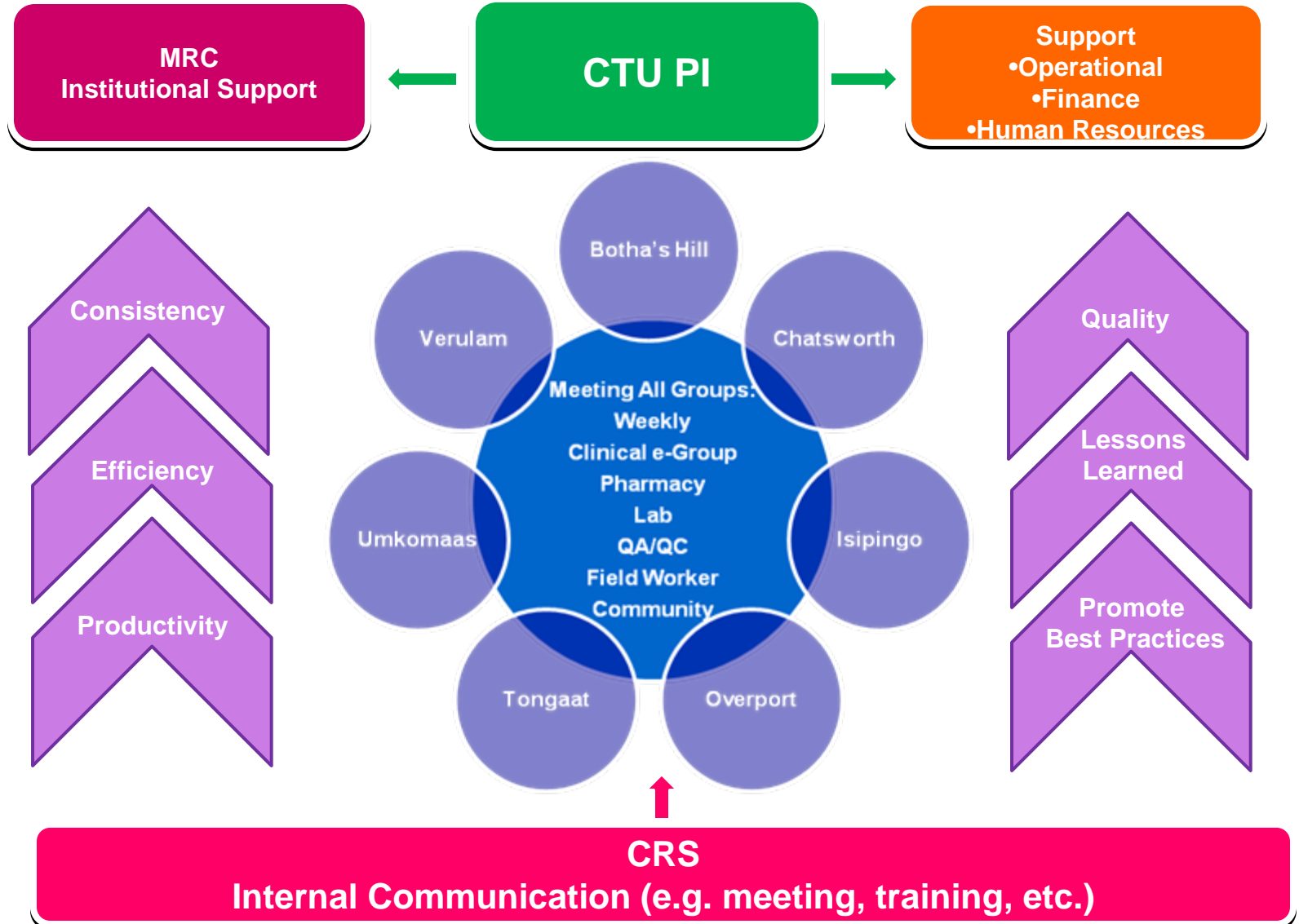
Sites will call C/LAB or OPS when first batch of samples are ready  
 Dispatch driver from Westville  
 Two drivers IATA certified to pick up samples from KZN N/S region  
 Unit driver to pick from Bothas Hills  
 Vehicle equipped to transport infectious specimens  
Back Up Plans  
 Sites completing blood draw late –overtime hours arrangement made

Travel time for KZN North Region 2 hours 30 min

Specimen in transit after first collection 1 hour 30 min

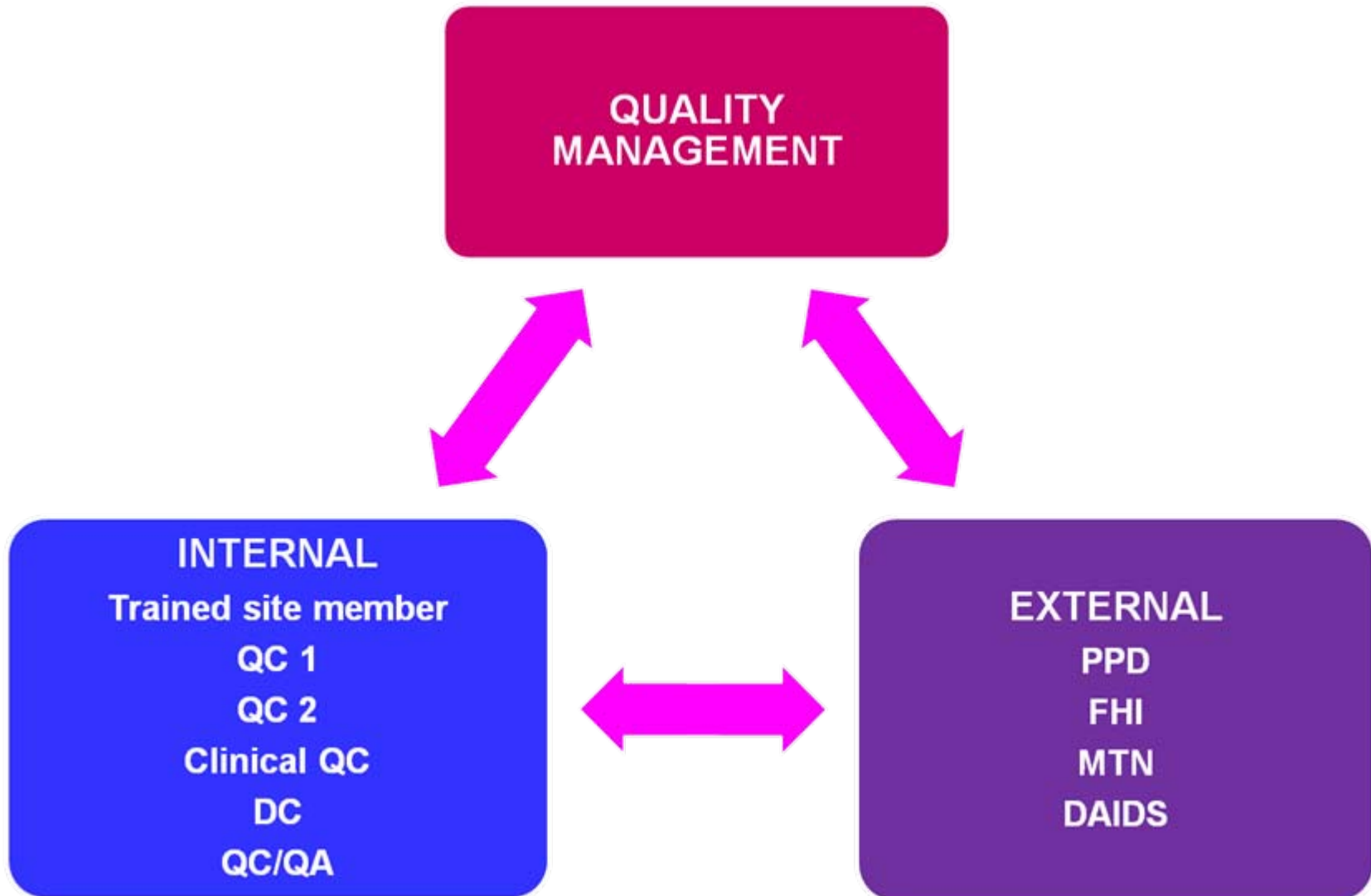
# COMMUNICATION IN A MULTI-SITE CTU

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# INTERNAL & EXTERNAL PROCESSES

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- **A constant need exists for the development of effective strategies in all aspects of clinical trial implementation>>>ongoing**
- **Communication is key in a multi-site multi-protocol CTU**
- **Improve strategies to follow up on participants to improve retention and adherence**
- **Need for multiple effective tools when implementing multiple protocols simultaneously**
- **Finger-printing system works! But also need back-up manual system**

- **High HIV prevalence>>>target new areas**
- **Ongoing communication with communities incl updating on results of completed trials**
- **Use internal communication and best practices to ensure good quality, high recruitment and retention strategies**
- **Multipronged approach to adherence counseling**
- **Involvement of male partners to improve retention and adherence, reduce social harm and address risk reduction however not losing sight that TNF gel and tabs is a product designed for women to be used by women**
- **A need exists for male involvement workshops but also we should think of workshops for women...to empower women, educate women that they do have choice**

**And this is probably the wonder of research,  
is that with every challenge comes new innovative ideas,  
every hurdle brings forth the formulation and provision of  
powerful tools and with every setback...  
renewed hope and optimism to continue the drive ahead  
and complete the task we set out to do.**

**THANK YOU!**

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