

# Challenges at CAPRISA eThekweni Clinical Research Site

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# Presentation Outline

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- Challenges Implementing VOICE
- Strategies to Address These Challenges
- Lessons Learned
- Unresolved Challenge

# Challenges Implementing VOICE

<b>Challenge</b>	<b>Ongoing or Resolved</b>	<b>Expected or Unexpected</b>
Adherence to oral study product	Ongoing	Expected
Recruitment: Negative cues/ misconceptions by key stakeholders, restructuring processes in stakeholder organizations, no show of potential participants after community outreach	Ongoing	Expected
Co-enrolment	Ongoing	Expected

# Strategies to Address These Challenges

<b>Challenge</b>	<b>Strategies</b>	<b>Successful or not?</b>
Adherence to oral study product	<ul style="list-style-type: none"><li>• Early follow up after enrolment</li><li>• Side effects pamphlet</li><li>• Communication log between pharmacy and clinic</li><li>• Clinic contact details well displayed and participants given contact cards</li></ul>	<p>Successful: Participant withdrawal from study = Nil</p> <p>Successful: Short term adherence issues resolved early on.</p>

# Strategies to Address These Challenges

<b>Challenge Recruitment</b>	<b>Strategies</b>	<b>Successful or not?</b>
Negative cues/ misconceptions by key stakeholders	Forums to discuss concerns	Positive feedback received
Restructuring processes in stakeholder organizations	<ul style="list-style-type: none"><li>• Continuous engagement</li><li>• Sharing resources and expertise</li><li>• Partnerships - Training/capacity building</li></ul>	Success evaluated on an ongoing basis
No show of potential participants after community outreach	Emphasize legitimacy of organization using CAPRISA leaflets and staff ID cards	Success still to be evaluated

# Strategies to Address These Challenges

Challenge	Strategies	Successful or not?
Co-enrolment	<ul style="list-style-type: none"><li>• Information provided during IC process</li><li>• IC declaration</li><li>• Co-enrolment questionnaire</li><li>• Old Citrix database</li><li>• New fingerprinting database</li><li>• Daily QC check</li></ul>	<p><u>System/User factors:</u> Citrix database – Overwriting or database down</p> <p>Fingerprinting database - Network link may be down</p> <p><u>Patient factors:</u> Fingerprinting database - Scan all 10 fingers</p>



# Lessons Learned

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## ■ Staffing:

- Start process of approval with regulatory bodies as early as possible
- Multi – tasking with adequate training
- Difficult to recruit and retain clinicians

## ■ Visit flow/length of study visit:

- Offer early clinics
- Split visits
- Reminders to participants to come in early
- Checklists revised to ensure smooth clinic flow.

## ■ Community involvement:

- Periodic engagement and feedback to communities necessary,

# Unresolved Challenge

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- **Other ideas on how to improve product adherence?**
- **How to maximize on community outreach activities?**

