

Community Response to Planned Clinical Study for a Phase I/II Study of the Safety, Tolerability, Acceptability and Pharmacokinetics of Oral and Long- Acting Injectable Cabotegravir and Rilpivirine in HIV +Virologically Suppressed Children 2- <12

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IMPAACT Annual Meeting



Purpose of the survey

Determine Community Response in relation to issues of Safety, Tolerability, Acceptability and Pharmacokinetics of Oral and Long- Acting Injectable Cabotegravir and Rilpivirine in HIV +Virologically Suppressed Children 2- <12 in City of Johannesburg – Sub= District D and Sub- District F

Survey Methodology

- ▶ Obtain information from respondents in the following demographics:
 - Youth- Age group- (12 years – 19 years)
 - Parents/ Caregivers/ Guardians(Age group 20 years – 29 Years)
 - Parents/ Caregivers/ Guardians(Age group 30 years – 39 years)
 - Parents/ Caregivers/ Guardians(Age group 40 years and above)

Respondents were taken from a diverse number of community members to obtain a clearer picture of different perspectives taking into consideration general LSMs, level of education, age and sexual orientation.

Summarized Community Responses

Does the summary clearly explain why the study is being done?

- ▶ YES it is- However, scientific comprehension will be a challenge for a layman
- ▶ YES- Clearly explained
- ▶ NO- Summary is not clear- what is the purpose of including parents/ guardians and caregivers of participants?

Considering the purpose of the study, are the study objectives appropriate?

- ▶ YES they are appropriate
- ▶ How will the CAB LA work?

Summarized Community Responses

Is the study target population appropriate based on the study objectives?

- ▶ Yes and no. Children's immune system is still at a developing stage to be tampered with, however, if the scientists closely monitor for any red flags it is appropriate
- ▶ Target population is appropriate except for the inclusion of parents/ caregivers. Not sure what their roles are.

What concerns do you have about the study if it is done in your community?

- ▶ Children have to be monitored closely, so resource mobilization is a great concern
- ▶ Will the community be willing to participate?
- ▶ There should be campaigns that will educate community members about the study and provide full information on the benefits of the study

Summarized Community Responses

What barriers or challenges do you anticipate for this study from your community?

- ▶ Lack of understanding of clinical trials and also whether CAB members will cascade the correct information
- ▶ Resistance from patients- whether they will adjust to their current therapy
- ▶ Target population may be hard to reach
- ▶ Communication and understanding

What barriers or challenges to retention do you anticipate in your community?

- ▶ Resources are the main potential barriers to retention
- ▶ Injection is not comfortable to most patients especially children- Defaulter rate might spiral out of control
- ▶ Negative sentiments from unreliable sources might hamper retention- The right questions should be asked to ensure participants fully understand the study objectives and benefits

Summarized Community Responses

Do you have concerns related to the study risks in this study?

- ▶ Just concerned about the adverse events and the possibility of them being permanent
- ▶ None currently
- ▶ None- as long as ethics clearance has been obtained
- ▶ In case of possibility of after effects how will participants be assisted

Will the study benefits be understandable for study participants and the community?

- ▶ As long as the message is clear and concise and no hidden information and agenda yes
- ▶ This will depend on the literacy level of the participants
- ▶ Yes- Only if the researchers provide the community with every information and clarity upfront

Summarized Community Responses

Would you encourage a family member to enroll in this study?

- ▶ Yes and No- It will depend on the information received and how it was communicated and if the people involved with working with children are from a credible institution I trust
- ▶ Yes- especially for the injection compared to daily orally taken pills
- ▶ Yes because in the long run it will reduce the risk of forgetting to take medication and also for those afraid of taking medication in front of partners or family

If this study is planned in your community, what reactions, if any, do you anticipate from stakeholders, government, local leaders, etc.?

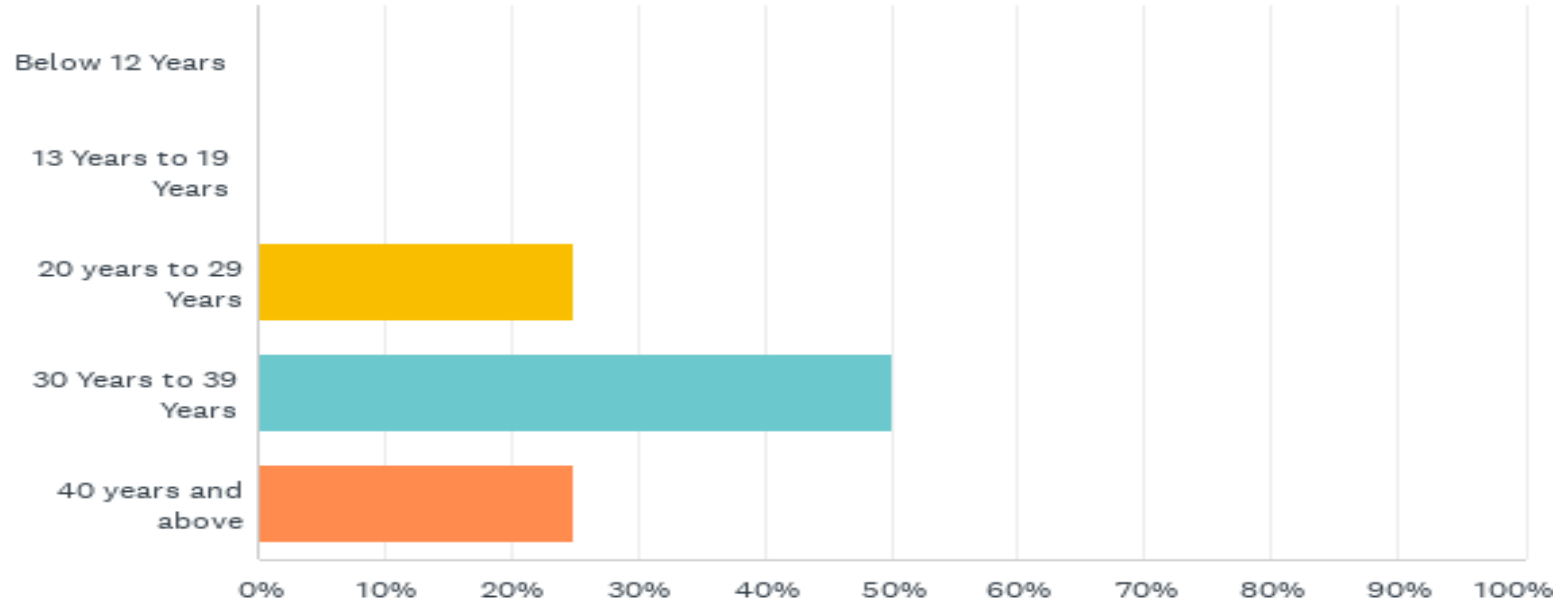
- ▶ Stakeholder management is key, therefore strategic approach would make every stakeholder buy-in to the research
- ▶ I don't anticipate any resistance if clear and honest information is shared
- ▶ I anticipate some resistance from traditional and religious leaders.

Summarized Community Responses

What additional feedback would you like to provide the research team?

- ▶ Is an incentive in any form going to be offered to participants, as a way of appreciation and encouragement?
- ▶ Please do research on how infants will also benefit
- ▶ I'm not sure if the parents/ caregivers participating in the study will be literate enough to understand the study objectives and provide adequate feedback to the researchers, what are steps taken to educate this category of participants and how will the researchers ascertain if they fully understand the study risks they are exposing their children to?

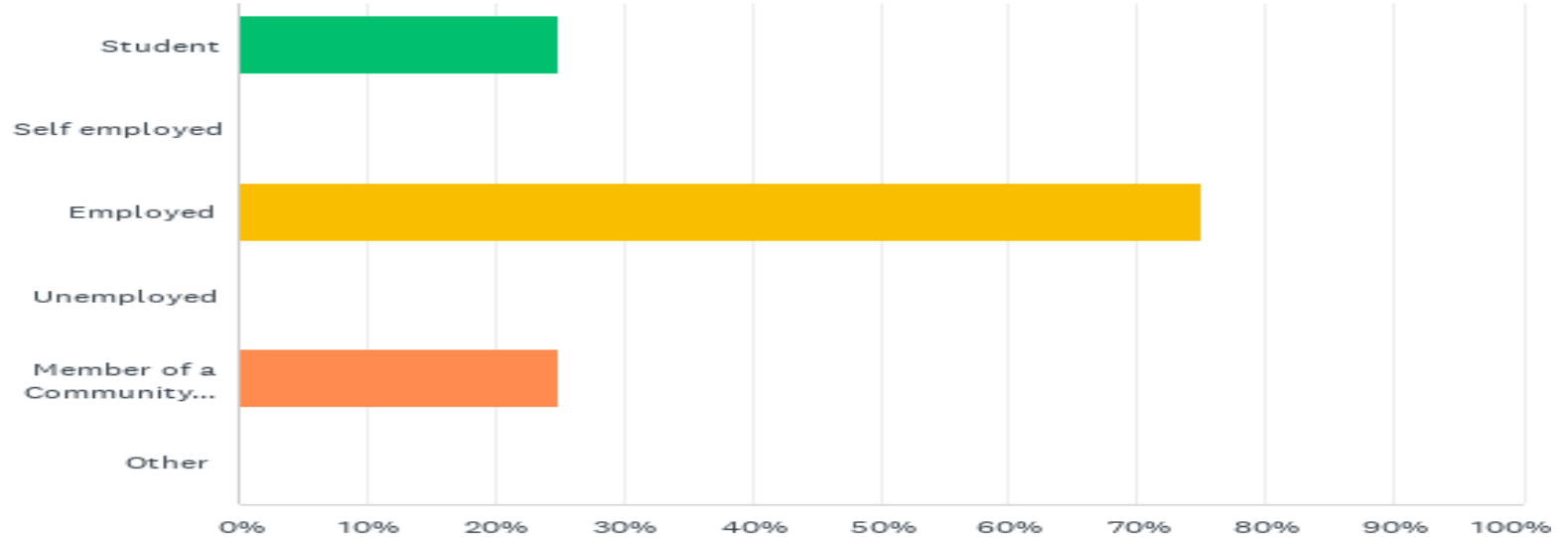
Under which age category do you fall?



Under which age category do you fall?

ANSWER CHOICES	RESPONSES	
Below 12 Years	0.00%	0
13 Years to 19 Years	0.00%	0
20 years to 29 Years	25.00%	1
30 Years to 39 Years	50.00%	2
40 years and above	25.00%	1
Total Respondents: 4		

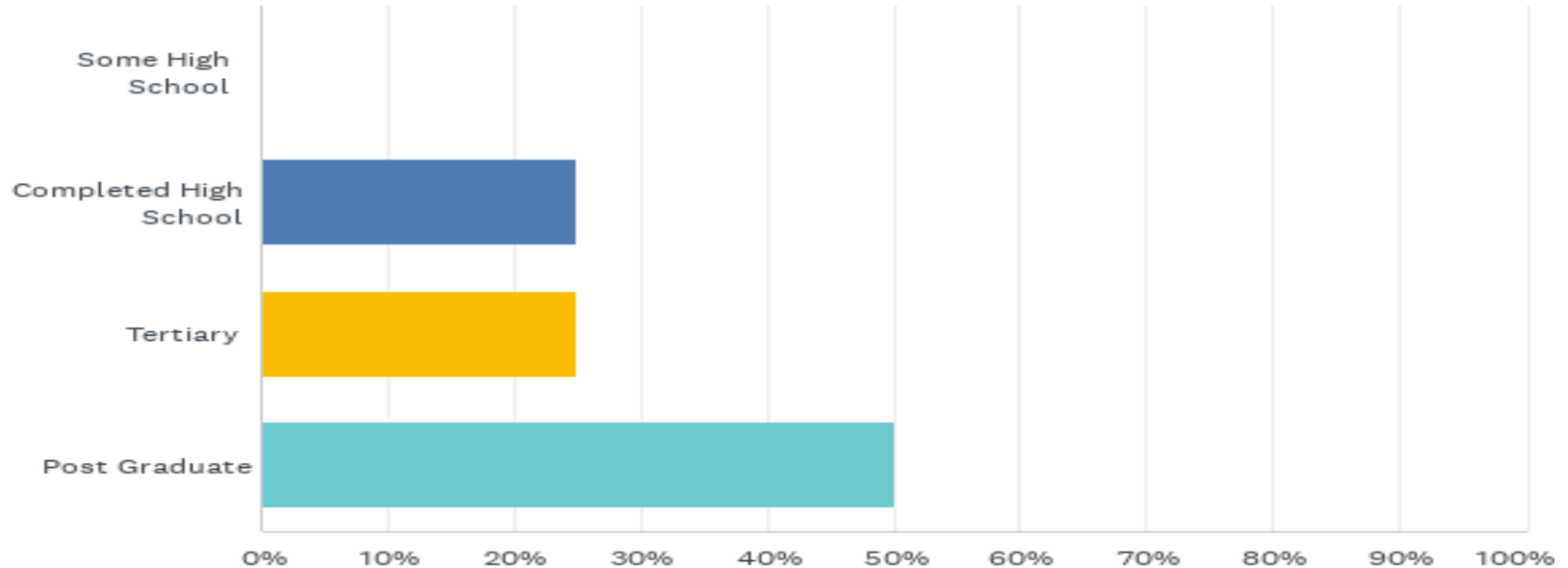
What is your occupation?



What is your occupation?

ANSWER CHOICES	RESPONSES	
Student	25.00%	1
Self employed	0.00%	0
Employed	75.00%	3
Unemployed	0.00%	0
Member of a Community Advisory Board	25.00%	1
Other	0.00%	0
Total Respondents: 4		

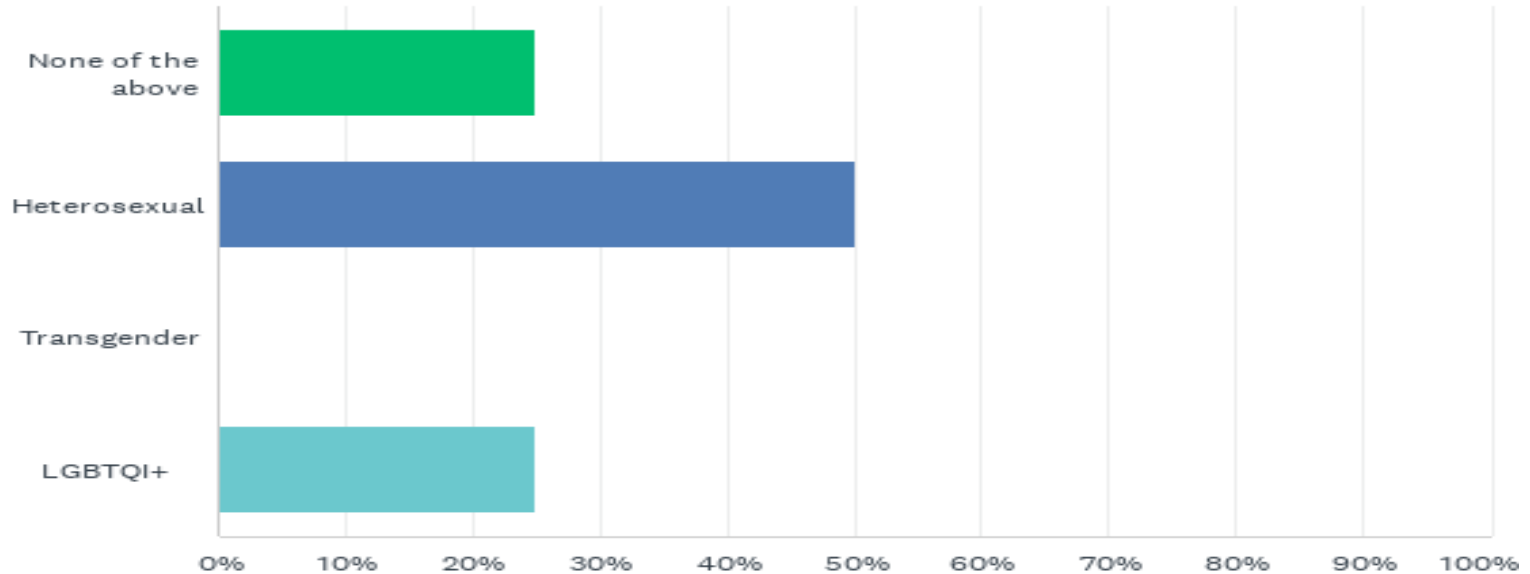
What is your level of education



What is your level of education

ANSWER CHOICES	RESPONSES	
Some High School	0.00%	0
Completed High School	25.00%	1
Tertiary	25.00%	1
Post Graduate	50.00%	2
TOTAL		4

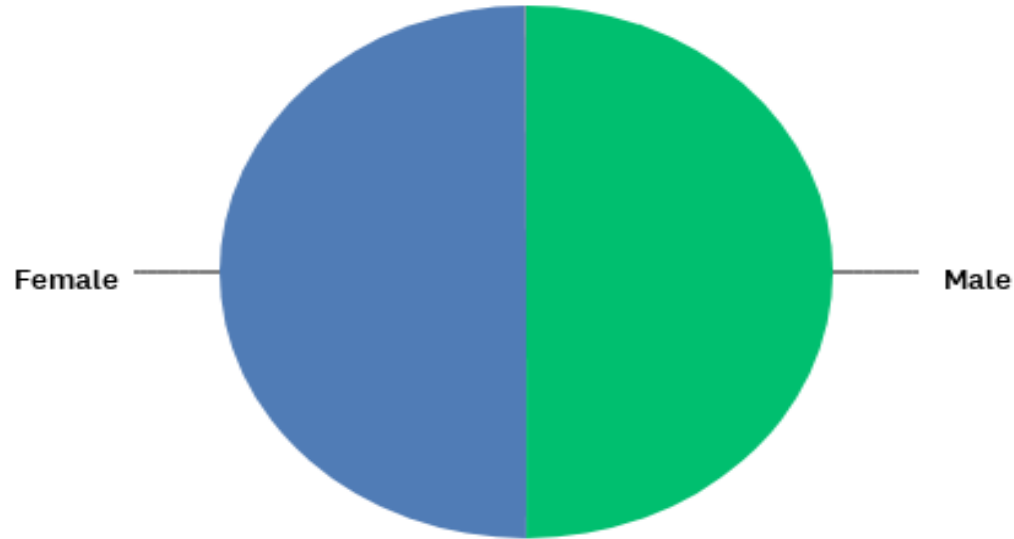
What is your sexual orientation?



What is your sexual orientation?

ANSWER CHOICES	RESPONSES	
None of the above	25.00%	1
Heterosexual	50.00%	2
Transgender	0.00%	0
LGBTQI+	25.00%	1
TOTAL		4

What is your gender



What is your gender

ANSWER CHOICES	RESPONSES	
Male	50.00%	2
Female	50.00%	2
Other (please specify)	0.00%	0
TOTAL		4

Thank You

Q&A

IMPAACT Annual **Meeting**

