

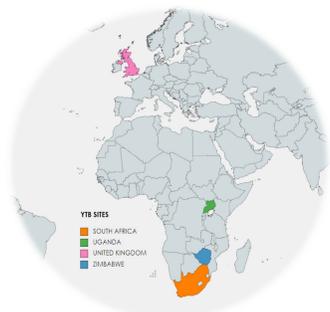
# Empowering adolescents living with HIV to effectively engage and participate in the development and delivery of clinical trials: A digital model during COVID.

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## Background

Adolescent research rarely engages adolescents living with HIV (ALHIV) muting their voice and input in decisions taken about their health. To start to address this, in 2017 **Fondazione Penta ONLUS (Penta)** developed a model of youth participation called the Youth Trials Boards (YTBs).

The main objective of the model is to create an environment where ALHIV have real influence in clinical trial research that impacts on them. The pilot was initiated with 4 groups from South Africa, Uganda, UK and Zimbabwe. Each comprised of 9 ALHIV between the ages of 15 – 19 years.



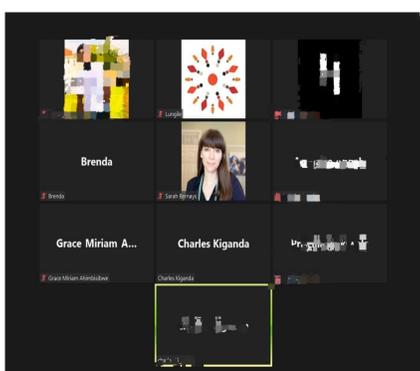
YTB members were trained on basic information about what is a clinical trial and understanding their HIV medication to enable them to give an informed view. Each site was facilitated by local coordinators and supported by an international core team. The international team worked closely with the clinical trials management teams linked to this work, actively ensuring that youth voice is part of the design and delivery of the research. The pilot was successful, and the model now runs as set out above.

## COVID-19 and how to maintain youth engagement

Prior to the COVID-19 pandemic, the project operated with in-person meetings. The pandemic made this either impossible (where countries were in lock-down) or presented significant risk to the adolescents and their families by asking them to travel t, and participate in, non-essential meetings.

This forced a rethink in how the model could continue to work during this time. Multiple assessments were undertaken to review the idea of digital meetings. Barriers to these included: adolescents not having equipment or data, adolescents not having the skills or knowledge to fully engage in digital meetings; potential personal risks to adolescents in providing expensive equipment to them. These assessments were conducted centrally and locally, to ensure we were engaging with the local situation in each country.

Through this process, it was felt that a digital model could work with the right level of support and consideration for the adolescents.



YTB members in each country were provided with tablets and a data allowance to enable them to participate on digital platforms. Digital training sessions were developed and conducted with the ALHIV from South Africa, Uganda and Zimbabwe to enable them to be able to properly engage and use their equipment efficiently.

Risk assessment processes were developed to be run with any site that was considering in-person meetings to ensure any risk was mitigated and that the adolescents' well-being was at the centre of this decision-making.

This enabled the adolescents to meet virtually in local meetings, but also meant we could start hosting global meetings, giving YTB members the opportunity to meet their peers in other countries and experience the functioning of YTB on a global level.

## Key outputs

Once the digital training was completed, we were able to either host digital meetings, as well as risk assess in-person meetings where COVID-19 levels were low and national policy allowed.

Using this hybrid model, YTBs have been able to play an important part in various clinical trials. ODYSSEY, Breather Plus, D3 and LATA trials have afforded the adolescents to showcase their capabilities in various ways. The most notable key outputs are as follows.

### Example one: Designing the LATA logo

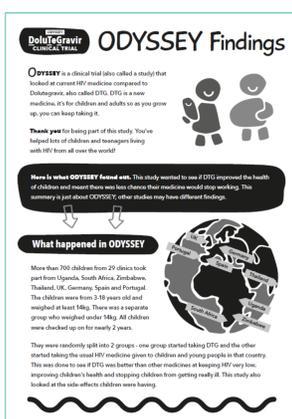
The aim of the LATA Study is to find out whether taking long-acting injectable medicines every 8 weeks is as effective and safe as taking tablet HIV medicines every day and that this has quality of life benefits to ALHIV. After carrying out a thorough risk assessment, this work began at an in-person meeting and successfully competed after various follow up digital meetings.

YTBs were able to bring to life a concept that carried deep meaning. Besides looking like a syringe the "T" in the LATA logo also includes a circle above that stands for unity.



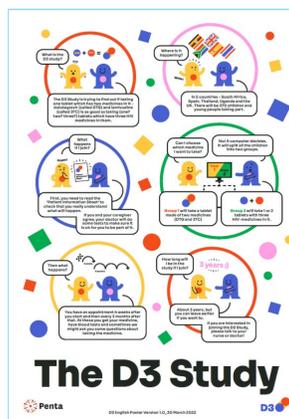
### Example two: ODYSSEY Findings sheets

ODYSSEY is a study evaluating the efficacy and safety of dolutegravir-based antiretroviral therapy compared with standard of care in children starting first- or second-line antiretroviral therapy in resource-limited and well-resourced settings. At the end of a study, clinical trials disseminate their findings through a letter to the participant. For ODYSSEY, YTBs were asked to create a summary sheet to replace this, with the important findings children and adolescents need to know. The ODYSSEY findings sheet was approved by some IRBs as additional material. Through the digital platform, YTB members were able to share ideas of that summary sheet should contain and how it must be presented.



### Example three: D3 Patient Information Poster

D3 is a global clinical trial which aims to find out whether treating children and adolescents living with HIV with two anti-HIV medicines, dolutegravir (DTG) and lamivudine (3TC), is as safe and as effective as the three-medicine anti-HIV treatments currently used in routine practice. This poster was designed during one of the few in-person meetings and subsequently completed through follow up meetings on the digital platform. It aims to explain the study simple to those under the age of 15.



For the YTB to succeed in creating a useful and meaningful resource they need to be equipped with the necessary knowledge and supported where they have gaps. At the end of the production line is numerous communications with the YTB, youth engagement team, trials team and the graphics designer. Checks and balances are put in – place to ensure that any material produced has accurate scientific information, is relevant and youth friendly.

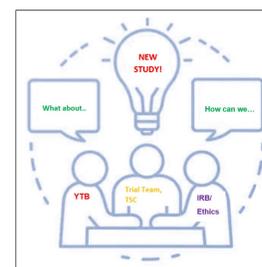
## Lessons learned

- Safely digitalising participation for low-income settings so that no adolescent was put at risk of having expensive equipment was a critical consideration.
- Digital interactions and engagement needed to be youth-friendly. Sessions needed to be planned to take the above into account.
- Challenges included connectivity, power cuts and 'digital shyness'.
- Facilitation of break out rooms in local languages to give optimum support was essential in being inclusive.

Digitalising the model presented a number of positive outcomes:

- Being able to support YTB members to acquire valuable digital knowledge and lifetime skills.
- Being able to bring researchers to the YTB members through having them engaged in meetings has been invaluable to both the engagement in research but also researchers understanding of youth engagement.

## Conclusion



Young people have a place at the table.

Community Advisory Boards for adults have been active in clinical trials in the past years, so the time for adolescents is long overdue. The material produced by YTB has shown the value the adolescents can bring and has also guided the adults to understand what the needs of the adolescents are. COVID-19 could have halted this work, but by digitalising we managed to continue this, whilst adding value to the model.

Digital adaptation of the model has provided ALHIV with digital skills that place them a step ahead of their country peers this platform also serves as a bridge between the scientist and YP on the ground.

The YTB's are continuing to work in-person and digitally, and have started to create additional materials for trials where they decide the format (videos) as well as content.

Allowing adolescents 'seats at the table' with the scientists means they have the opportunity to share their lived-experience as partners. This was able to continue through the pandemic and the experience forced us to develop and strengthen this delivery model of youth engagement.

## References

- ODYSSEY [www.mrcctu.ucl.ac.uk/studies/all-studies/o/odyssey-penta20](http://www.mrcctu.ucl.ac.uk/studies/all-studies/o/odyssey-penta20)
- BreatherPlus [www.mrcctu.ucl.ac.uk/studies/all-studies/b/breather-plus](http://www.mrcctu.ucl.ac.uk/studies/all-studies/b/breather-plus)
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- SHIELD [www.penta-id.org/hiv/shield](http://www.penta-id.org/hiv/shield)



To find out more about Youth Engagement and Patient Involvement at Penta

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