‘Nothing about us without us’: Multi-country adolescent patient-led recruitment information in the Long-Acting Treatment in Adolescents(LATA) trial – an animated video to compliment ‘traditional’ participant information.

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Background

LATA (NCT05154747), which started enrolment in May 2023, is the largest randomised trial of long-acting injectable antiretroviral therapy (ART) in virologically suppressed adolescents aged 12-19 years living with HIV-1. It has a dedicated work package on patient engagement and works with groups of adolescents living with HIV through ‘Youth Trials Boards (YTB)’ in South Africa, Uganda and Zimbabwe (and soon in Kenya).

Image: LATA logo designed by young people

The YTB model brings together condition specific adolescent patients, offers them cohesive training, support and youth-friendly meetings to enable them to fully engage with the development and delivery of clinical trials and research.

Clinical trials and research must provide clear and understandable patient information when recruiting for studies. Participant information sheets and consent forms in paediatric and adolescent clinical research are predominantly produced by adults. There can be a discrepancy between what the Independent Review Boards (IRBs) legally require, what pharmaceutical companies legally require and what the patients need to be able to properly understand and make an informed decision on being part of a study. Young people report they do not understand most of the information provided, so do not read it, and rely on conversations with trusted Healthcare Providers to make their decisions.

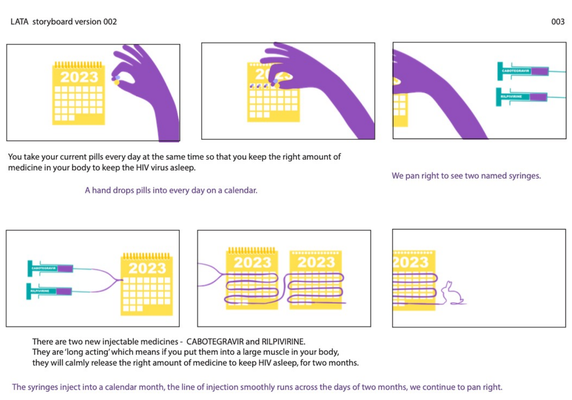
Traditional Patient Information Sheets and Consent forms (PIS&C) can be long and detailed, a format young people across the YTB project have said they cannot understand or engage with. In LATA, a new direction was followed. The traditional PIS&C was produced (as demanded by the regulatory bodies), but with accompanying support documents co-created by the YTB groups.

Image: Still from video

Methods

Youth Trials Board members in LATA attended a global digital meeting with representatives from South Africa, Uganda and Zimbabwe. They immersed themselves in the trial and explored what information they felt young people needed to know and how this should be presented.

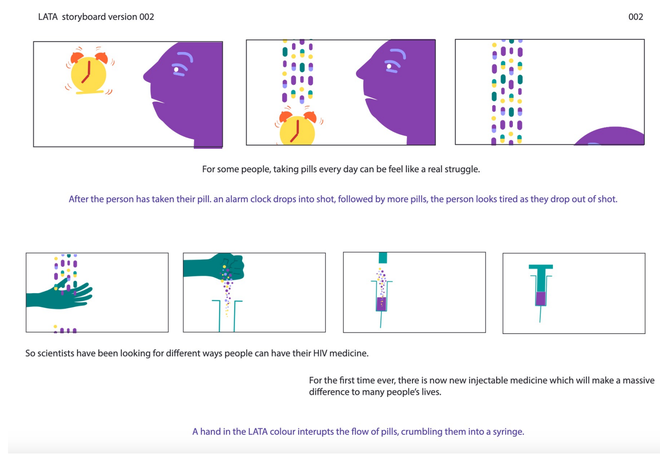
Image: Example of a story board and draft script sent to YTB groups and Trial Management Team.



The group were unanimous that young people prefer to get their information through videos. They also felt that, to make an informed decision about LATA, young people needed to have:

- Education on how long-acting medication has been developed and works.
- Understand the efficacy of 2-monthly injection compared to daily pills in suppressing HIV.
- Information about possible additional side-effects.
- A clear explanation to understand where and how the injection would be administered.
- A short summary about the trial, as this is covered in detail in the PIS.

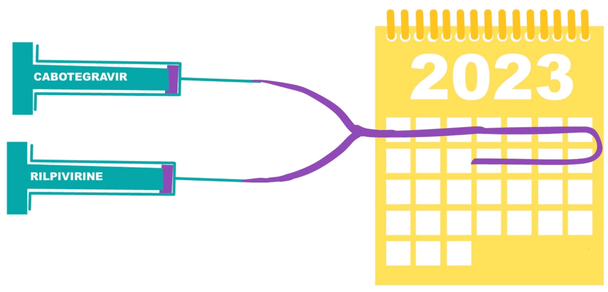
Image: Example of a story board and draft script sent to YTB groups and Trial Management Team.



Due to the content that would be included, and the varied countries the study is running in, they felt that the best way to explain this would be through animation.

The methodology used to create this video was youth engagement model, with experts through experience (the young people) and experts through training (scientists and film-makers) co-creating the video with co-ordination from the Penta Youth Engagement team. This combination ensured the film was both scientifically and medically correct, but also clear and youth-friendly.

Image: Still from video

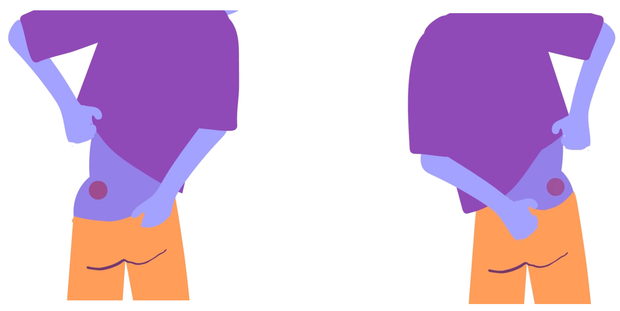


Results

The final videos are 5-6 minutes long (depending on language). The script and animation was developed through the young people establishing the content areas, then the trial management team providing the medical and scientific information needed. Using storyboards, a process of alternating script and image drafting, science-checks and youth-checks happened over three months.

Once finalised, the scripted was translated from English into Shona, Isizulu, Swahili and Luganda. Each trial site then sent the story board with final script to their IRB for an initial ethics check. This was to mitigate any possible ethics issues prior to building the final video.

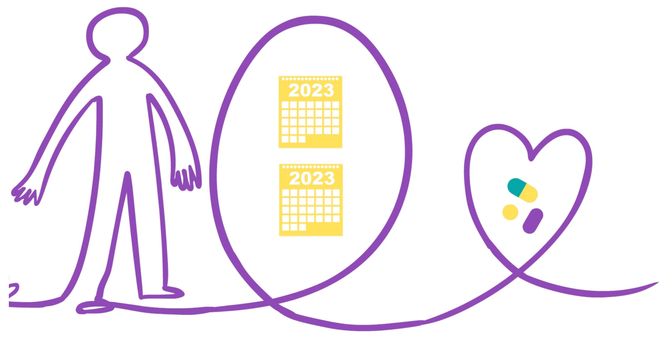
Image: Stills from video



YTB members were then invited to record the voice overs in their first language to ensure these were authentic and the animation was completed.

All the national ethics committees approved the video. All sites using the videos are collating patient and study staff feedback to see how useful, helpful and impactful the video has been.

Image: Still from video



Conclusions

Although the process of co-production of this animation was time consuming, the end result is something children, young people and their caregivers can genuinely understand and engage with.

The process allowed the young people to decide from the start what format and content should be included, whilst ensuring it also correctly represented the trial. Some of the information young people highlighted they needed to know was not part of what regulatory bodies and trials teams had included in the PIS&S. This raises the question of whether patients should be engaged in decision-making on the content of PIS’s in future studies.

We have mandated that all sites show this video to potential participants, and we are formally capturing information on how useful participants and as applicable (depending on their age) their carers’ found this video.

The assent or consent to be part of LATA is truly ethical, coming from a place of full understanding and awareness, rather than making decisions based on conversations with trusted Healthcare Providers.

While this video is an adjunct to the PIS&C, in future, videos such as this could replace much of the lengthy complex language provided to trial participants, this merits further discussion with ethics committees and regulators.

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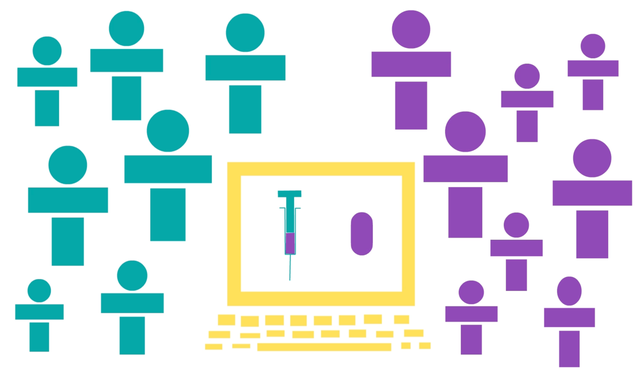

To find out more about LATA please visit the MRC/CTU University College London website www.mrcctu.ucl.ac.uk/studies/all-studies/l/lata

To find out more about Youth Engagement and Patient Involvement work at Penta scan QR code

Penta has since produced Quality Standards for the ethical and meaningful participation of children and young people in clinical trials and research to support rolling-out of this practice. penta-id.org/patient-involvement-quality-standards/

THANK YOU

All the YTB members, past and present, in South Africa, Zimbabwe, Uganda and UK
Site coordinators and staff at: Enhanced Care Foundation, Durban; MUJ-HU, Baylor and JCRC in Kampala; UZCRC, Harare; CHIVA, UK.
The Trial Teams for LATA, at Medical Research Council, Clinical Trials Unit at University College London.
The LATA Consortium: Penta Foundation, Italy; MRC CTU at UCL, Institute of Clinical Trials and Methodology, UCL, London, UK; Joint Clinical Research Centre, Kampala, Uganda; University of Zimbabwe Clinical Research Centre, Harare, Zimbabwe; Moi University, Eldoret, Kenya; Department of Paediatrics and Child Health, King Edward VIII Hospital, University of KwaZulu-Natal, Durban, South Africa; Baylor College of Medicine Children’s Foundation-Uganda, Kampala, Uganda; Africa Health Research Institute, Durban, South Africa; Uganda Virus Research Institute, Entebbe, Uganda; London School of Hygiene and Tropical Medicine, London, UK; MU-JHU Care Ltd.
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To the film maker: Bigger House https://www.biggerhousefilm.co.uk/