

PARTICIPANT INFORMATION LEAFLET

On behalf of Chelsea and Westminster Hospital NHS Foundation Trust we would like to thank you for your ongoing participation in the PrEP Impact Trial. Your involvement is crucial to the success of the trial. The PrEP Impact Trial ends in October 2020. However, the last date study drug can be provided to participants will be on 12th July and the final study visits for the majority of participants will occur between 13th July and 12th October 2020. Due to the COVID-19 pandemic some participants had to be provided with more than 3 months' supply due to safety and local access reasons. We will be asking these participants to still attend their 3 month visit as expected even if they still have study drug remaining; there will be no requirement to return any remaining study drug. Please take time to read the following information carefully and discuss it with others, if you wish.

- Part 1 tells you how you will be able to access PrEP at your last study visit.
- Part 2 provides information on who to contact if you have any questions about the trial or non-trial PrEP.

Part 1

1) How will I access PrEP at my last study visit?

A fully commissioned PrEP programme has been agreed for England. Due to the current situation it may be that the programme will not be fully operational at the same time in all clinics across England. Therefore, there will be an 'interim' supply available for Impact participants with ongoing PrEP need who cannot immediately access PrEP via the commissioned programme. This has been provided to the clinics free of charge by NHSE. More information will be published on the PrEP Impact Trial website (<https://www.prepimpacttrial.org.uk>).

Both to ensure delivery of the planned Impact trial outcomes and to access ongoing PrEP it is important that all participants attend their final trial visit between 13th July and 12th October 2020. In your final trial visit you will undergo the same study procedures as usual.

- **How can I get PrEP once I finish the trial?**

You will be able to access PrEP through the national programme or where this is not yet in place through the interim supply from your local clinic. Your clinician will advise you how this is being managed locally.

- **Should I carry on taking PrEP?**

Yes, if your risk continues. If you feel your circumstances have changed and you are no longer at risk, you do not need to carry on taking PrEP. If in the future your risk increases for whatever reason, you should contact a sexual health clinic to discuss restarting PrEP. If you have PrEP (study drug) remaining after the end of the trial we will not be asking you to return it, however, you should check the expiry date of any PrEP you have before using it. It is very important you have an HIV test before restarting PrEP if you have had any risk at all since stopping. You should also ensure you understand how to start PrEP correctly. For more information please refer to i-base website (<http://i-base.info/guides/prep>).

- **How will I get my test results from my last study visit?**

You will get your results in the same way you do currently from your local Sexual Health Clinic. You should continue to access full sexual health screening every 3 months if you are sexually active.

Part 2

- **If I have questions about the trial who should I contact?**

You should ask the Principal Investigator or trial research staff at your clinic (their contact details are on the Participation Information Sheet and Consent Form) or the local clinic staff if you have any questions about the study. Please check your local clinic website for information/contact details. You can also access the study website which has further information and updates regarding the PrEP Impact Trial (<https://www.prepimpacttrial.org.uk>).

- **If I have questions about getting PrEP after the trial who should I contact?**

For any questions that you have regarding PrEP supply/access after the trial has ended please contact your local clinic staff.