

## An update on the PrEP trial – June 2017

We continue to make progress preparing for the pre-exposure prophylaxis (PrEP) Impact Trial. The work being undertaken now will provide a solid base to deliver a robust study. The PrEP Programme Oversight Board provides governance to make sure the PrEP trial is as good as it can be and that it progresses as planned.

The Board met on 5 May and 2 June 2017, and the following key points were discussed:

- To ensure the trial is robust, plans including the protocol, financial impact and measurement of results were shared with the National Institute for Health Research (NIHR) for their input. Their constructive feedback at the June meeting will be incorporated into the final plans.

The Programme Oversight Board subsequently approved the trial protocol and budget, subject to consideration and, where appropriate, inclusion of NIHR's suggestions, and once finalised the protocol will be submitted to a Research Ethics Committee for approval.

NIHR will continue to attend future meetings as advisors to the Board.

- A timeline for next steps will be produced by the trial team, co-ordinated by St Stephen's Clinical Research, part of St Stephen's AIDS Trust, who are working with researchers to co-ordinate and lead the trial.
- NHS England emphasised that the PrEP trial is a top priority for the organisation and is leading the drug procurement for the trial. A pre-tender procurement supplier event was held in April, which was well attended by a number of manufacturers. Because of the value of the contract, EU procurement rules apply and as such the formal Prior Information Notice (PIN) was published in the Official Journal of the European Union on 30 May 2017. The PIN invites interested parties to submit applications to provide the drug for the trial. NHS England expects to be able to confirm the award of the final contract by 31 July 2017, meaning trial drugs could be available from early August, in readiness for the trial to begin once ethics approval is received and trial sites are prepared.
- Budget discussions focused on the maximum sum available (up to £10m) and the research and drugs costs.
- Public Health England reported that all specialised genitourinary medicine clinics (i.e. level 3 sexual health clinics) were written to with information on the trial and have received notification from only one clinic to opt out. All other respondents have demonstrated a willingness to be included as a trial site.
- The importance of including laypeople at all levels of governance and decision-making was discussed and agreed. A recruitment process is underway to ensure lay representation at future meetings of the PrEP Programme Oversight Board and any working groups. Paul Martin of the LGBT Foundation has agreed to be an interim lay member until appointments are made.
- The need to ensure regular communications with stakeholders was discussed and the Board committed to producing an update following each meeting. A frequently

asked questions document to address some of the more detailed queries that have been received will be available shortly.

The PrEP Programme Oversight Board will meet again in July and an update will follow.

For further information on the trial, please contact [prepimpacttrial@ststcr.com](mailto:prepimpacttrial@ststcr.com)