STAMP Trial Summary Sheet: Screening with TAMPons: Evaluating Diagnostic Accuracy for STIs, BV and HPV and Assessing Participant Views

We would like to invite you to take part in this research trial which aims to investigate whether a tampon can be used to diagnose a range of common vaginal infections: HPV (Human Papillomavirus), BV (bacterial vaginosis) chlamydia and gonorrhoea. The tampon sample will be compared with two types of vaginal swab, one which you will take yourself, and one that will be taken by a female trial nurse.

WHAT YOU NEED TO KNOW

- The purpose of this study is to find out whether the DAYE Diagnostic Tampon (DDT) can be used to find out if you have a range of common vaginal infections (HPV, BV, chlamydia and gonorrhoea).
- There is 1 face to face visit at a clinic in London, all other contact with the trial team will be via online forms (approximately 5 forms throughout the course of the study) and remote video/telephone calls (if needed, not mandated). Study participation is expected to last around 2-4 weeks.
- We plan to enrol 350 participants in this trial.
- Taking part is voluntary and you can withdraw at any time.

REQUIREMENTS TO TAKE PART

- Aged 25-65
- Sexually active - defined as having penetrative vaginal sex
- No hysterectomy or allergy/sensitivity to tampons
- Not pregnant or breastfeeding

WHAT DOES TAKING PART IN THE STUDY MEAN?

- The trial will last for approximately 2-3 weeks.
- You will be asked to complete some online forms and 2 online questionnaires.
- All participants will have 3 samples taken as part of the trial: the DDT, a self-swab and a clinician administered swab taken by a female trial nurse. You should not be on your period when you take the samples or visit the clinic.
- Different participants will be asked to swab in a different order, for example self-swab first or DDT first. This order will be randomly assigned.
- Once you have completed the trial you will be paid £50, as well as reasonable travel expenses up to £50.

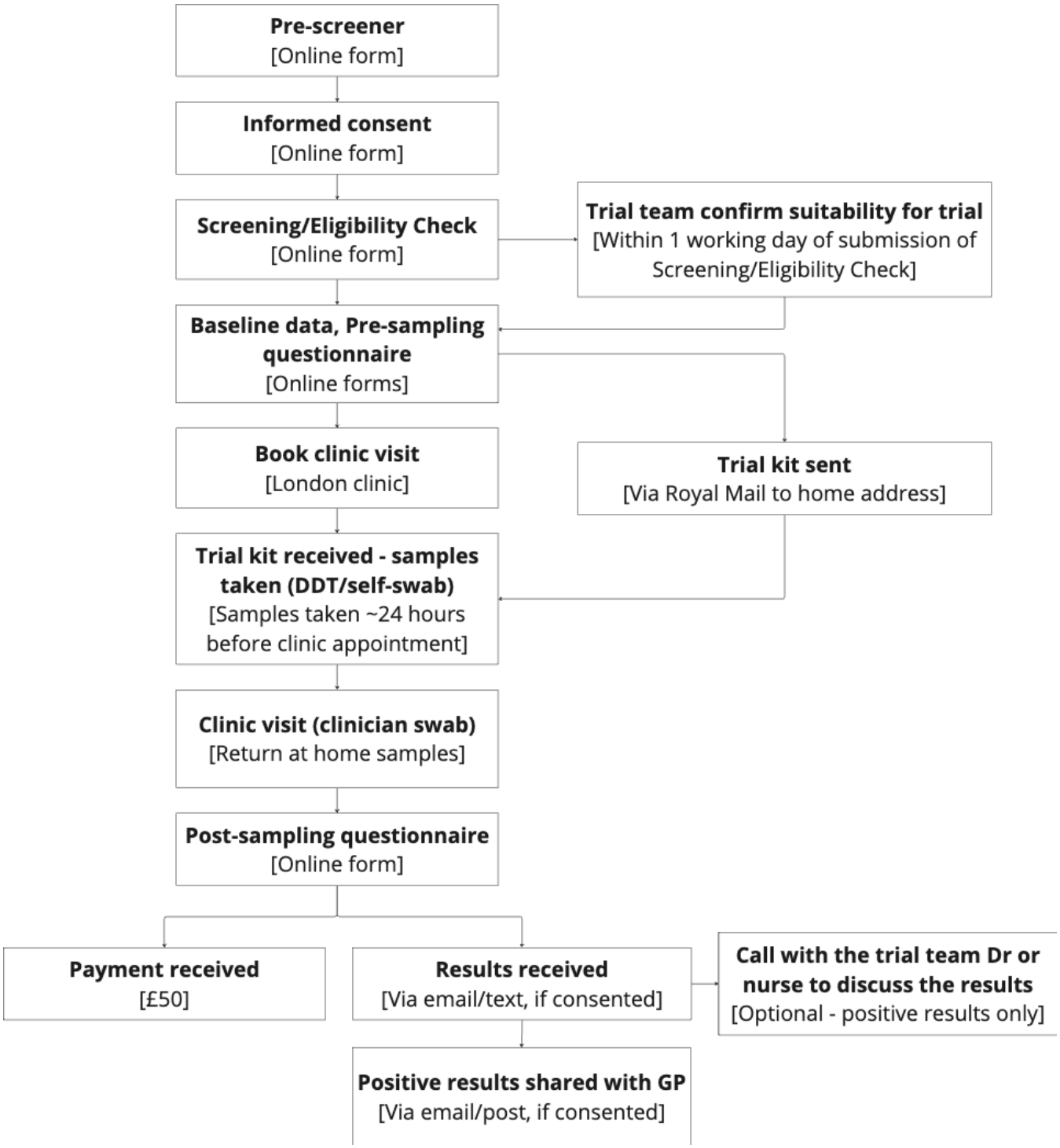
CONFIDENTIALITY & DATA PROTECTION

People allowed to look at your health information will be limited, to include the research team, the Sponsor, and the regulatory authorities who check that the trial is being carried out correctly. Your GP will be informed of your participation in the trial.

TO TAKE PART:

- Complete a short form on the internet to check that you are eligible.
- Read this information sheet in full and talk to others about the trial if you wish.
- Provide your consent and you will be sent the initial trial forms to fill in.

STAMP Trial Participant Flowchart



Need more information?

If you would like to speak to a member of the trial team, please feel free to get in touch:

Freephone: 0808 189 3802 Email address: STAMP@lindushealth.com