PARTICIPANT QUESTIONNAIRE – 6 MONTHS

Please complete this questionnaire 6 months after starting your study treatment.

Date of questionnaire completion (dd-mmm-yyyy): __ __ - __ __ __ - __ __ __ __

Thank you very much for taking the time to answer these questions for the VITA study.
Please be assured that all the data collected remains confidential. The VITA website is secure and only the study team have access to the information you are entering.

Please answer the questions as fully as possible. This should take approximately 10 minutes to complete.

If you have any problems please contact the trial team on vitahelp@nottingham.ac.uk

BACTERIAL VAGINOSIS (BV) SYMPTOMS - RESOLUTION

<table>
<tr>
<td>Had your original BV symptoms cleared by 3 months i.e. when you completed the 3 month questionnaire?

By "original" we mean your BV symptoms at the beginning of the study (before treatment)</td>
<td>Choose one of the following 4 options:

1. ☐ My original BV symptoms had cleared by 3 months.

2. ☐ My original BV symptoms did not clear in the first 3 months but they did clear by 6 months <u>without additional treatment.</u>

3. ☐ My original BV symptoms did not clear in the first 3 months but they did clear by 6 months <u>with additional treatment.</u>

If you ticked option 2 or 3 please confirm the date they cleared:

| __ | __ | | __ | __ | __ | | __ | __ | __ | __ |

ⓘ If you answered <u>option 1, 2, or 3,</u> please complete the section on "BV Symptoms - Recurrence" below and then continue to complete the rest of the questionnaire.

4. ☐ My original BV symptoms never cleared and are ongoing

ⓘ If you answered <u>option 4</u> please do NOT answer the section on "BV Symptoms – Recurrence" below but go straight to the section on "Additional Medications for your BV" and then complete the rest of the questionnaire.</td>
</tr>
</table>

BACTERIAL VAGINOSIS (BV) SYMPTOMS - RECURRENCE

Have you experienced any **new** episodes of bacterial vaginosis symptoms **in the last 3 months**?	Yes* ☐ No☐
***If YES, please answer the following questions:**	
What was the date of your first new episode of bacterial vaginosis symptoms (in the last 3 months)?	__ __ / __ __ __ / __ __ __ __
How many new episodes of bacterial vaginosis type symptoms have you experienced (in the last 3 months)?	__ __
In total, approximately how many weeks have you had bacterial vaginosis symptoms (in the last 3 months)?	☐ Less than 1 Week ☐ 1 to less than 2 Weeks ☐ 2 to 4 Weeks ☐ More than 4 Weeks
Were the recurrence(s) of your bacterial vaginosis symptoms typical of your usual symptoms?	☐ Always ☐ Sometimes ☐ Seldom

ADDITIONAL MEDICATIONS FOR YOUR BV

<table>
<tr><td>In addition to your study treatment, have you used any additional medications for your BV in the last 3 months?

(Either prescribed to you by a doctor or bought over the counter e.g. bought separately in a pharmacy or online)</td><td>☐Yes* ☐No</td></tr>
<tr><td colspan="2">*If YES, please select the additional medication below:</td></tr>
<tr><td rowspan="5"></td><td>☐ Metronidazole tablets

Were these prescribed? ☐Yes ☐No

Number of courses taken? ☐☐</td></tr>
<tr><td>☐ Metronidazole vaginal gel

Was this prescribed? ☐Yes ☐No

Number of courses taken? ☐☐</td></tr>
<tr><td>☐ Lactic acid vaginal gel
(e.g. Balance Activ®, Relactagel®, Canesbalance®)

Was this prescribed? ☐Yes ☐No

Number of courses taken? ☐☐</td></tr>
<tr><td>☐ Clindamycin cream
(e.g. Dalacin)

Was this prescribed? ☐Yes ☐No

Number of courses taken? ☐☐</td></tr>
<tr><td>☐ Other – please specify:

Was this prescribed? ☐Yes ☐No

Number of courses taken? ☐☐</td></tr>
</table>

ANTIBIOTICS	
Have you received any **antibiotics for any other condition/illness (not your BV)** in the last 3 months?	☐ Yes* ☐ No
***If YES, please select the antibiotic below:**	
☐ **Amoxicillin** Was this prescribed? ☐Yes ☐No	
☐ **Flucloxacillin** Was this prescribed? ☐Yes ☐No	
☐ **Doxycycline** Was this prescribed? ☐Yes ☐No	
☐ **Other – Please specify:** Was this prescribed? ☐Yes ☐No	

THRUSH	
Have you developed **vaginal thrush in the last 3 months?**	☐Yes* ☐No *If yes please specify the date of onset (when the thrush started): |__|__| |__|__|__| |__|__|__|__| How many episodes of vaginal thrush have you had? |__|__|

Have you performed vaginal douching **in the last 3 months** (by vaginal douching, we mean washing inside your vagina)?	☐ Yes ☐ No

SEXUAL CONTACT

Have you had sex **in the last 3 months**?	☐ Yes* ☐ No
***If YES, please answer the following questions:**	
If yes, did you use condoms:	☐ Yes* ☐ No *If yes did you use condoms: ☐ Always (including oral sex) ☐ Not for oral sex but otherwise always ☐ Sometimes
Have you had any new sexual partners **in the last 3 months**?	☐ Yes ☐ No

Have you been diagnosed with HIV in the last 3 months?	☐Yes ☐No

Have any of the following been diagnosed **in the last 3 months**? Please answer yes or no for each condition.		
Gonorrhoea	☐Yes* ☐No	*If yes Number of episodes:
Chlamydia	☐Yes* ☐No	*If yes Number of episodes:
Trichomonas	☐Yes* ☐No	*If yes Number of episodes:
Pelvic inflammatory disease	☐Yes* ☐No	*If yes Number of episodes:

USE OF HEALTH SERVICES FOR YOUR BV

Please record how many face-to-face or telephone consultations you have had with each of the following NHS services **in the last 3 months?**
Only include those consultations that are related to your bacterial vaginosis or study treament.

(please do not record your original visit where you were first prescribed your treatment).

NHS SERVICE	Service used?	*If YES, provide details:	
		Face-to-face contact (please record the number of times)	Telephone contact (please record the number of calls)
GP appointment	☐Yes* ☐No		
Nurse (GP Surgery) appointment	☐Yes* ☐No		
Specialist sexual health clinic appointment (e.g. GUM clinic)	☐Yes* ☐No		
NHS outpatient appointment (other than a specialist sexual health clinic/GUM clinic)	☐Yes* ☐No		
NHS walk in centre	☐Yes* ☐No		
NHS 111	☐Yes* ☐No		
GP out of hours service	☐Yes* ☐No		
Pharmacy	☐Yes* ☐No		
A & E Department	☐Yes* ☐No		
Other – Please specify:	☐Yes* ☐No		

HOSPITAL ADMISSIONS – BV	
In the last 3 months, have you been to hospital for an overnight stay because of problems related to your **bacterial vaginosis**?	☐ Yes* ☐ No
***If yes, please answer the questions below:**	
NHS or private hospital?	☐ NHS hospital ☐ Private hospital
Number of nights you stayed in hospital?	
Reason(s) for your stay(s) in hospital:	

SF-12™ QUESTIONNAIRE

Validated SF-12™ (4 week) Quality of Life questionnaire

– End of 6 month Questions –

THANK YOU

Thank you for completing this questionnaire. Your continued participation in the study is very much appreciated.

If your contact details have changed in the last 3 months please let us know by emailing: vitahelp@nottingham.ac.uk

This is your final questionnaire so you will not receive any further questionnaires to complete.

Other Comments
If you have any other comments about the study, please let us know below:
____
____
____

Medical Attention
If you require any medical attention, please contact your GP/sexual health centre

Thank you for completing this questionnaire.