PARTICIPANT QUESTIONNAIRE – WEEK 2

TREATMENT ALLOCATION: LACTIC ACID GEL

Please complete this questionnaire 2 weeks 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

STUDY TREATMENT

This section refers to your allocated study treatment.

LACTIC ACID GEL	
Which brand of lactic acid gel did you use?	☐Balance Activ® ☐Relactagel® ☐Canesbalance® ☐Other – please specify:
What date did you start using your lactic acid gel? (dd-mmm-yyyy)	_____ _____ _____
Treatment confirmation	**Lactic acid gel used?**
Day 1 (Start of treatment)	☐ Yes ☐ No
Day 2	☐ Yes ☐ No
Day 3	☐ Yes ☐ No
Day 4	☐ Yes ☐ No
Day 5	☐ Yes ☐ No
Day 6	☐ Yes ☐ No
Day 7	☐ Yes ☐ No
Did you complete your course of lactic acid gel? * If you answered no, please select why:	☐ Yes ☐ No* ☐ I accidentally missed applying the gel ☐ I didn't like using the gel ☐ Side effects of the gel ☐ Other – please specify:
How easy did you find using the lactic acid gel?	☐ Very easy ☐ Easy ☐ Neither easy nor difficult ☐ Difficult ☐ Very difficult

BACTERIAL VAGINOSIS (BV) SYMPTOMS

Have your BV symptoms cleared and stayed cleared **following your study treatment**?	☐ **Yes** – If yes what was the date they cleared? (dd-mmm-yyyy) __ __ __ __ __ __ __ __ __ ☐ **No** – If no how are your symptoms today compared to when you started study treatment? ☐ Better but not cleared/disappeared ☐ Improved initially but worsened again ☐ No change ☐ Worse

Are any of the following present today?	A genital discharge which you think is not normal: ☐Yes ☐No An offensive vaginal smell (a smell that is unpleasant to you): ☐Yes ☐No Vaginal irritation (may include itching/pain/burning): ☐Yes ☐No

SIDE EFFECTS – STUDY TREATMENT

NAUSEA		
During treatment, did you feel nauseous or sick?	☐ Yes* ☐ No	
***If YES, please answer the following questions:**		
How long after starting study treatment did you first feel nauseous or sick?	☐ Less than 2 hours ☐ 2 to less than 6 hours ☐ 6 to less than 24 hours ☐ 1 to 3 days ☐ More than 3 days	
How did the nausea/sickness affect you?	☐ Able to eat normally ☐ Ability to eat or drink fluids significantly decreased ☐ Unable to eat or drink fluids	
Approximately how long did your nausea/sickness last, in hours **or** days?	Hours __ __	Days __ __
Is your nausea/sickness fully resolved now?	☐ Yes ☐ No	

VOMITING		
During treatment, did you experienced any vomiting?	☐ Yes* ☐ No	
***If YES, please answer the following questions:**		
How long after starting study treatment did your vomiting start?	☐ Less than 2 hours ☐ 2 to less than 6 hours ☐ 6 to less than 24 hours ☐ 1 to 3 days ☐ More than 3 days	
How severe was your vomiting?	☐ 1 episode in 24 hours ☐ 2 to 5 episodes in 24 hours ☐ 6 or more episodes in 24 hours or need IV fluids	
Approximately how long did your vomiting last in total, in hours **or** days (i.e. from the first time you vomited to the last time?)	Hours ⌊__⌋	Days ⌊__⌋
Is your vomiting fully resolved now?	☐ Yes ☐ No	

TASTE / ABNORMAL TASTE		
During treatment, did you have any changes in taste or experience abnormal taste?	☐ Yes* ☐ No	
***If YES, please answer the following questions:**		
How long after starting study treatment did the change in taste/abnormal taste start?	☐ Less than 2 hours ☐ 2 to less than 6 hours ☐ 6 to less than 24 hours ☐ 1 to 3 days ☐ More than 3 days	
How severe was the change in your taste/abnormal taste?	☐ Mild ☐ Moderate ☐ Severe	
Approximately how long did the change in your taste/abnormal taste last, in hours **or** days?	Hours ⌊__⌋	Days ⌊__⌋
Is your change in taste/ abnormal taste fully resolved now?	☐ Yes ☐ No	

VAGINAL IRRITATION (may include itching/pain/burning)		
During treatment, did you experience any vaginal irritation?	☐ Yes* ☐ No	
***If YES, please answer the following questions:**		
How long after starting study treatment did your vaginal irritation start?	☐ Less than 2 hours ☐ 2 to less than 6 hours ☐ 6 to less than 24 hours ☐ 1 to 3 days ☐ More than 3 days	
How severe was the vaginal irritation?	☐ Mild ☐ Moderate ☐ Severe	
Approximately how long did the vaginal irritation last, in hours **or** days?	Hours ___	Days ___
Is your vaginal irritation fully resolved now?	☐ Yes ☐ No	

ABDOMINAL PAIN		
During treatment, did you experience any abdominal pain?	Yes* ☐ No ☐	
***If YES, please answer the following questions:**		
How long after starting study treatment did your abdominal pain start?	☐ Less than 2 hours ☐ 2 to less than 6 hours ☐ 6 to less than 24 hours ☐ 1 to 3 days ☐ More than 3 days	
How severe was the abdominal pain?	☐ Mild ☐ Moderate ☐ Severe	
Approximately how long did the abdominal pain last, in hours **or** days?	Hours ___	Days ___
Is your abdominal pain fully resolved now?	☐ Yes ☐ No	

DIARRHOEA		
During treatment, did you experience any diarrhoea?	☐ Yes* ☐ No	
***If YES, please answer the following questions:**		
How long after starting study treatment did your diarrhoea start?	☐ Less than 2 hours ☐ 2 to less than 6 hours ☐ 6 to less than 24 hours ☐ 1 to 3 days ☐ More than 3 days	
How severe was the diarrhoea?	☐ Mild ☐ Moderate ☐ Severe	
Approximately how long did the diarrhoea last, in hours **or** days?	Hours ⌊__⌋	Days ⌊__⌋
Is your diarrhoea fully resolved now?	☐ Yes ☐ No	

ADDITIONAL MEDICATIONS FOR YOUR BV

In addition to your study treatment, have you used any additional medications for your BV since joining the study? (Either prescribed to you by a doctor or bought over the counter e.g. bought separately in a pharmacy or online)	☐Yes* ☐No
***If YES, please select the additional medication below:**	
	☐ **Metronidazole tablets** Were these prescribed? ☐Yes ☐No Number of courses taken? ⌊__⌋
	☐ **Metronidazole vaginal gel** Was this prescribed? ☐Yes ☐No Number of courses taken? ⌊__⌋
	☐ **Lactic acid vaginal gel** (e.g. Balance Activ®, Relactagel®, Canesbalance®) Was this prescribed? ☐Yes ☐No Number of courses taken? ⌊__⌋
	☐ **Clindamycin cream** (e.g. Dalacin) Was this prescribed? ☐Yes ☐No Number of courses taken? ⌊__⌋
	☐ **Other – please specify:** Was this prescribed? ☐Yes ☐No Number of courses taken? ⌊__⌋

ANTIBIOTICS	
Have you received any **antibiotics for any other condition/illness (not your BV)** since starting your study treatment?	☐ 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** since starting your study treatment?	☐ Yes* ☐ No
***If YES, please select thrush treatment taken below:**	
☐ **No treatment taken**	
☐ **Clotrimazole** (e.g. Canesten) Was this prescribed? ☐Yes ☐No	
☐ **Fluconazole** (e.g. Diflucan) Was this prescribed? ☐Yes ☐No	
☐ **Itraconazole** (e.g. Sporanox) Was this prescribed? ☐Yes ☐No	
☐ **Other – Please specify:** Was this prescribed? ☐Yes ☐No	

Are you pregnant?	☐ Yes ☐ No

Have you performed vaginal douching since starting study treatment (by vaginal douching, we mean washing inside your vagina)?	☐ Yes ☐ No

SEXUAL CONTACT

Have you had sex since starting study treatment?	☐Yes* ☐No
***If YES, please answer the questions below:**	
If yes, how soon after starting study treatment did you first have sex?	☐ I had sex the same day as starting my study treatment If not the same day please specify how many days after study treatment you first had sex: ____ | ____
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 since starting study treatment?	☐ Yes ☐ No

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 since you started the study treatment.
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 two weeks since starting your study treatment, have you been to any 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:	

HOSPITAL ADMISSIONS – STUDY TREATMENT	
In the two weeks since starting your study treatment, have you been to any hospital for an overnight stay because of side effects linked to your **study treatment**?	☐ 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 Acute (1 week) SF-12™ Quality of Life Questionnaire

YOUR WEEK 2 VAGINAL SAMPLES

Have you taken your week 2 vaginal samples at the time of completing this questionnaire?

IF YES:

☐ **Yes – I have taken my week 2 samples**	
What date did you **take** your week 2 samples?	
Have you **posted** your week 2 samples? *If yes, what date were they **posted**? (dd-mmm-yyyy)	☐ Yes* ☐ No
If you have not yet posted your week 2 samples please do so as soon as possible	

IF NO:

☐ **No – I have NOT yet taken my week 2 samples**	
If no, please specify why (select one of the options):	☐ I have not yet taken my week 2 samples but I will do so ☐ I can't remember how to take my week 2 samples (*Please refer to your kit instruction leaflet and the instructional video on **www.vitastudy.org** Please contact your local site team if you need additional advice)* ☐ I have lost my sample kit *(Please contact vitahelp@nottingham.ac.uk) for a replacement kit)* ☐ I will not be taking my 2 week samples – please specify reason:
If you have not yet taken your week 2 samples please do so as soon as possible	

– End of Week 2 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 2 weeks* please *let us know by emailing:*
vitahelp@nottingham.ac.uk

We will send you another questionnaire in 3 months.

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.