Clinical and cost-effectiveness of **DE**sogestrel versus the combined oral contraceptive pill for problem **B**leeding on the etonogestrel **I**mplant (The **DEBI** Trial)

90 days Questionnaire

Participant Initials: | | | |

Participant ID: | | | | | |

Questionnaire completion date: | | | | | | | | | |
D D M M M Y Y Y Y

Sponsor: University of Nottingham

90 days Questionnaire Version: v2.0

Follow-up 90 days

1. Self-reported categorisation of problem bleeding in previous 90 days	
Over the last 90 days how would you best describe your menstrual bleeding pattern? *Each time you had bleeding or spotting for one or more days in a row (with no bleeding for the day before or after), that counts as one episode.*	☐ No bleeding ☐ Less than 3 episodes ☐ 3-5 episodes ☐ 6 or more episodes ☐ 1 or more episode(s) lasting 14 days or more
2. Participant perception of bleeding pattern	
Compared with your first DEBI clinic visit with problem bleeding **approximately 90 days ago**, how is your menstrual bleeding pattern **now**?	☐ Improved significantly ☐ Improved slightly ☐ No change ☐ Worsened slightly ☐ Worsened significantly
3. Global impression of treatment	
During the past 90 days, how acceptable did you find taking the trial drug? (Please tick (✓)/or select) the one best response). Think about how appropriate, suitable, convenient, and how effective your trial treatment is, when deciding about the acceptability of your treatment.	☐ Totally unacceptable ☐ Unacceptable ☐ Slightly unacceptable ☐ Neutral ☐ Slightly acceptable ☐ Acceptable
4. Self-reported categorisation of problem bleeding in previous 30 days In addition to being interested in your experience for the duration of the trial we are also interested in your experiences over the last 30 days.	
Over the last **30 days** how would you best describe your menstrual bleeding pattern? *Each time you had bleeding or spotting for one or more days in a row (with no bleeding for the day before or after), that counts as one episode.*	☐ No bleeding ☐ 1 episode ☐ 2 or more episodes ☐ 1 or more episode(s) lasting 14 days or more
5. Adverse effects of treatment (Acceptability)	
5a. Since completing your last DEBI questionnaire **approximately 30 days ago**, have you experienced any of the following symptoms?	
Headaches	☐ Yes ☐ Mild ☐ Moderate ☐ Severe ☐ No

Nausea	☐ Yes ☐ Mild ☐ Moderate ☐ Severe ☐ No
Breast tenderness	☐ Yes ☐ Mild ☐ Moderate ☐ Severe ☐ No
Mood changes	☐ Yes ☐ Mild ☐ Moderate ☐ Severe ☐ No
Increased blood pressure	☐ Yes ☐ Mild ☐ Moderate ☐ Severe ☐ No
Hair thinning or loss	☐ Yes ☐ Mild ☐ Moderate ☐ Severe ☐ No
Fluid retention in ankles/feet	☐ Yes ☐ Mild ☐ Moderate ☐ Severe ☐ No
Bloating	☐ Yes ☐ Mild ☐ Moderate ☐ Severe ☐ No

Weight change	☐ Yes ☐ Mild ☐ Moderate ☐ Severe ☐ No
Acne	☐ Yes ☐ Mild ☐ Moderate ☐ Severe ☐ No
Other Please specify: ……	☐ Yes ☐ Mild ☐ Moderate ☐ Severe ☐ No

6. Implant adherence	
Have you had your implant removed in the last 30 days?	☐ Yes; date of removal: DD/MMM/YYYY ☐ No
7. Healthcare resource use	
7a. Have you contacted any NHS health services (e.g. GP, GP nurse or specialist clinic) about your implant/ problem bleeding or your study treatment in the last 30 days? (please do not record your original visit where you were first prescribed your treatment)	☐ Yes- please complete section **7b**. ☐ No – please move to section **7c.**
7b. If yes – NHS service contacted about problem bleeding or study treatment:	
GP appointment	☐ Yes – face-to- face (no of visits:_____) ☐ Yes – virtual (phone call/ video) (no of visits:_____) ☐ No
Nurse (GP Surgery) appointment	☐ Yes – face-to- face (no of visits:_____) ☐ Yes – virtual (phone call/ video) (no of visits:_____) ☐ No
Specialist sexual health clinic appointment (e.g. GUM clinic)	☐ Yes – face-to- face (no of visits:_____) ☐ Yes – virtual (phone call/ video) (no of visits:_____) ☐ No
Women's Health Hubs	☐ Yes – face-to- face (no of visits:_____) ☐ Yes – virtual (phone call/ video) (no of visits:_____) ☐ No
Community gynaecology clinic	☐ Yes – face-to- face (no of visits:_____) ☐ Yes – virtual (phone call/ video) (no of visits:_____) ☐ No
NHS outpatient appointment (other than a specialist sexual health clinic/GUM clinic /community gynaecology or women's health hub)	☐ Yes – face-to- face (no of visits:_____) ☐ Yes – virtual (phone call/ video) (no of visits:_____) ☐ No
NHS walk in centre	☐ Yes – face-to- face (no of visits:_____) ☐ Yes – virtual (phone call/ video) (no of visits:_____) ☐ No

NHS 111	☐ Yes – face-to- face (no of visits:_____) ☐ Yes – virtual (phone call/ video) (no of visits:_____) ☐ No
GP out of hours service	☐ Yes – face-to- face (no of visits:_____) ☐ Yes – virtual (phone call/ video) (no of visits:_____) ☐ No
Pharmacy	☐ Yes – face-to- face (no of visits:_____) ☐ Yes – virtual (phone call/ video) (no of visits:_____) ☐ No
A & E Department	☐ Yes (no of visits:_____) ☐ No
Other Please specify: ……	☐ Yes (no of visits:_____) ☐ No
7c. In the last 30 days have you bought any treatments or products in relation to problem bleeding, such as additional pads, tampons, painkillers etc (i.e. paid out of pocket)?	☐ Yes-please complete question **7d** ☐ No-please move to question **8**

7d. If you have bought any treatments or products in relation to problem bleeding, please estimate the total cost to the nearest pound.	Please tick if bought	Overall cost paid by you (£)
Pads, tampons, liners	☐ Yes	
Menstrual cup(s)	☐ Yes	
Underwear	☐ Yes	
Painkillers	☐ Yes	
Iron supplements	☐ Yes	
Other 1- please write in		
Other 2- please write in		

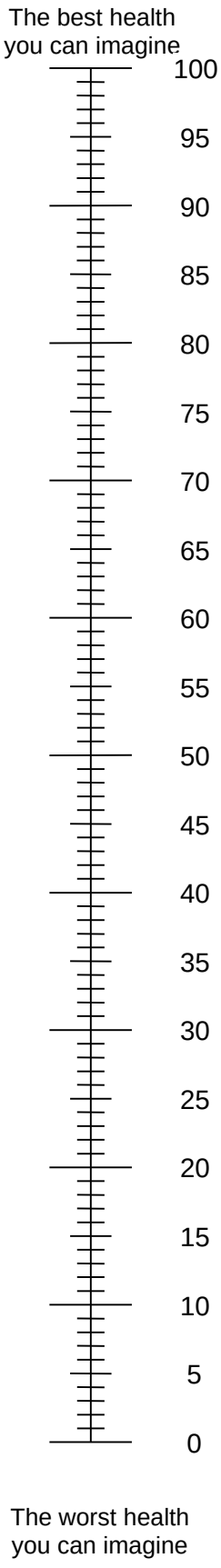
8. Health related quality of life (EQ-5D-5L)

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY	
I have no problems in walking about	
I have slight problems in walking about	
I have moderate problems in walking about	
I have severe problems in walking about	
I am unable to walk about	
SELF-CARE	
I have no problems washing or dressing myself	
I have slight problems washing or dressing myself	
I have moderate problems washing or dressing myself	
I have severe problems washing or dressing myself	
I am unable to wash or dress myself	
USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*	
I have no problems doing my usual activities	
I have slight problems doing my usual activities	
I have moderate problems doing my usual activities	
I have severe problems doing my usual activities	
I am unable to do my usual activities	
PAIN / DISCOMFORT	
I have no pain or discomfort	
I have slight pain or discomfort	
I have moderate pain or discomfort	
I have severe pain or discomfort	
I have extreme pain or discomfort	
ANXIETY / DEPRESSION	
I am not anxious or depressed	
I am slightly anxious or depressed	
I am moderately anxious or depressed	
I am severely anxious or depressed	
I am extremely anxious or depressed	

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
  0 means the worst health you can imagine.
- Please mark an X on the scale to indicate how your health is TODAY.
- Now, write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = ☐



9. About your overall quality of life (ICECAP-A)

Please indicate which statements best describe your overall quality of life at the moment by placing a tick (✓) in **ONE** box for each of the five groups below.

1. Feeling settled and secure

I am able to feel settled and secure in **all** areas of my life		4
I am able to feel settled and secure in **many** areas of my life		3
I am able to feel settled and secure in **a few** areas of my life		2
I am **unable** to feel settled and secure in **any** areas of my life		1

2. Love, friendship and support

I can have **a lot** of love, friendship and support		4
I can have **quite a lot** of love, friendship and support		3
I can have **a little** love, friendship and support		2
I **cannot** have **any** love, friendship and support		1

3. Being independent

I am able to be **completely** independent		4
I am able to be independent in **many** things		3
I am able to be independent in **a few** things		2
I am **unable** to be at all independent		1

4. Achievement and progress

I can achieve and progress in **all** aspects of my life		4
I can achieve and progress in **many** aspects of my life		3
I can achieve and progress in **a few** aspects of my life		2
I **cannot** achieve and progress in **any** aspects of my life		1

5. Enjoyment and pleasure

I can have **a lot** of enjoyment and pleasure		4
I can have **quite a lot** of enjoyment and pleasure		3
I can have **a little** enjoyment and pleasure		2
I **cannot** have **any** enjoyment and pleasure		1

Please ensure you have only ticked **ONE** box for each of the five groups.

10.Medications

The following questions are about medications you may have taken in addition to your trial medication over the last 30 days.

*You do **NOT** need to tell us about the following medications:*
Paracetamol, proton pump inhibitors, vitamins, opioids, H1 receptor antagonists (e.g. cyclizine, loratadine, chlorphenamine), H2 receptor antagonists (e.g. ranitidine), laxatives (osmotic or stimulant), anti-depressants – selective serotonin re-uptake inhibitors or tricyclic or venlafaxine, inhaled or topical corticosteroids, insulin, biguanides e.g. metformin, anti-fungal drugs, emollients, iron, anti-emetics – dopamine D2 receptor antagonists e.g. metoclopramide, domperidone, anti-psychotics (1st or 2nd generation), loperamide, aciclovir, nicotine

Have you taken any medication in addition to your trial medication over the last 30 days?	☐ Yes - please complete 8a-8k ☐ No - please go to the end of the questionnaire
10a. Non-steroidal Anti-inflammatory Drugs (NSAIDs) including:	
Ibuprofen	☐ Yes Number of days taken in last 30 days: ……
Mefenamic acid	☐ Yes Number of days taken in last 30 days: ……
Naproxen	☐ Yes Number of days taken in last 30 days: ……
Diclofenac	☐ Yes Number of days taken in last 30 days: ……
Celecoxib	☐ Yes Number of days taken in last 30 days: ……
Aspirin	☐ Yes Number of days taken in last 30 days: ……
Piroxicam	☐ Yes Number of days taken in last 30 days: ……
Other NSAID	☐ Yes Name……. Number of days taken in last 30 days: ……
10b. Tranexamic acid	☐ Yes Number of days taken in last 30 days: ……
10c. Tetracycline antibiotics	
Doxycycline	☐ Yes Number of days taken in last 30 days: ……
Lymecycline	☐ Yes Number of days taken in last 30 days: ……

10d. Liver enzyme inducing medicines which are inducers of the cytochrome CYP3A4 and CYP450 including: anticonvulsants, antibiotics, antifungals, systemic glucocorticosteroids, antiretrovirals and immunosuppressants	
Anticonvulsants:	
Phenytoin	☐ Yes Number of days taken in last 30 days: ……
Fosphenytoin	☐ Yes Number of days taken in last 30 days: ……
Primidone	☐ ☐ Yes Number of days taken in last 30 days: ……
Rufinamide	☐ Yes Number of days taken in last 30 days: ……
Carbamazepine	☐ Yes Number of days taken in last 30 days: ……
Eslicarbazepine	☐ Yes Number of days taken in last 30 days: ……
Oxcarbazepine	☐ Yes Number of days taken in last 30 days: ……
Phenobarbitone	☐ Yes Number of days taken in last 30 days: ……
Cenobamate	☐ Yes Number of days taken in last 30 days: ……
Topiramate	☐ Yes Number of days taken in last 30 days: ……
Lamotrigine	☐ Yes Number of days taken in last 30 days: ……
Antibiotics:	
Rifampicin	☐ Yes Number of days taken in last 30 days: ……
Rifabutin	☐ Yes Number of days taken in last 30 days: ……
Antifungals:	
Griseofulvin	☐ Yes Number of days taken in last 30 days: ……
Systemic glucocorticosteriods:	
Prednisolone	☐ Yes Number of days taken in last 30 days: ……
Dexamethasone	☐ Yes Number of days taken in last 30 days: ……
Hydrocortisone	☐ Yes Number of days taken in last 30 days: ……

Antiretrovirals:	
Efavirenz	☐ Yes Number of days taken in last 30 days: ……
Ritonavir	☐ Yes Number of days taken in last 30 days: ……
Immunosuppressants :	
Tacrolimus	☐ Yes Number of days taken in last 30 days: ……
Other CYP450 inducers:	
St John's Wort	☐ Yes Number of days taken in last 30 days: ……
Modafinil	☐ Yes Number of days taken in last 30 days: ……
Bosentan	☐ Yes Number of days taken in last 30 days: ……
Aprepitant	☐ Yes Number of days taken in last 30 days: ……
Lumacaftor	☐ Yes Number of days taken in last 30 days: ……
Statins	☐ Yes Number of days taken in last 30 days: ……
Other CYP450 inducers	☐ Yes Name……. Number of days taken in last 30 days: ……
Anticoagulants including:	
Warfarin	☐ Yes Number of days taken in last 30 days: ……
Low molecular weight heparin (lmwh)	☐ Yes Number of days taken in last 30 days: ……
Heparin or direct oral anticoagulants(doacs)	☐ Yes Number of days taken in last 30 days: ……
Other anticoagulants	☐ Yes Number of days taken in last 30 days: ……
10e. Hormones including:	
Progestogens (other than the etonogestrel implant)	☐ Yes Number of days taken in last 30 days: ……
Estrogens	☐ Yes Number of days taken in last 30 days: ……

Testosterone	☐ Yes Number of days taken in last 30 days: ……
Other hormones	☐ Yes Name……. Number of days taken in last 30 days: ……
10f. Gonadotrophin-releasing hormone (GnRH) analogues including:	
Leuprorelin	☐ Yes Number of days taken in last 30 days: ……
Triptorelin	☐ Yes Number of days taken in last 30 days: ……
Other GnRH analogues	☐ Yes Name……. Number of days taken in last 30 days: ……
10g. Selective progestogen receptor modulators including:	
Ulipristal acetate	☐ Yes Number of days taken in last 30 days: ……
10h. GLP-1 agonists including:	
Tirzepatide	☐ Yes Number of days taken in last 30 days: ……
Semaglutide	☐ Yes Number of days taken in last 30 days: ……
Exenatide	☐ Yes Number of days taken in last 30 days: ……
Liraglutide	☐ Yes Number of days taken in last 30 days: ……
Dulaglutide	☐ Yes Number of days taken in last 30 days: ……
Lixisenatide	☐ Yes Number of days taken in last 30 days: ……
Other GLP-1 agonists	☐ Yes Number of days taken in last 30 days: ……
10i. Depot Medroxy-Progesterone Acetate (DMPA)	☐ Yes Number of days taken in last 30 days: ……
10j. Tamoxifen	☐ Yes Number of days taken in last 30 days: ……
10k. Any other medication taken in the last 30 days not mentioned above	☐ Yes - please complete details below ☐ No
Name……. Number of days taken in last 30 days: ……	Name……. Number of days taken in last 30 days: ……
11.Treatment continuation	

Do you intend to continue with your allocated treatment?	☐ Yes ☐ No

Thank you for taking the time to complete your DEBI 90 days questionnaire.

Please return this to us in the prepaid envelope provided.

DEBI Trial
Nottingham Clinical Trials Unit
Applied Health Research Building
School of Medicine
University of Nottingham
Nottingham, NG7 2RD