

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)

### 60 days Questionnaire

Participant Initials:

Participant ID:

Questionnaire completion date:

Sponsor: University of Nottingham<sup>P</sup> D M M M Y Y Y Y

60 days Questionnaire Version: v2.0

Participant initials:

Participant ID:

### Follow-up 60 days

#### 1. Self-reported categorisation of problem bleeding in previous 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

#### 2. Participant perception of bleeding pattern

Compared with your first DEBI clinic visit with problem bleeding **approximately 60 days ago**, how is your menstrual bleeding pattern **now**?

- Improved significantly
- Improved slightly
- No change
- Worsened slightly
- Worsened significantly

#### 3. Adverse effects of treatment (Acceptability)

**3a.** 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

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Increased blood pressure	<input type="checkbox"/> Yes <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> No
Hair thinning or loss	<input type="checkbox"/> Yes <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> No
Fluid retention in ankles/feet	<input type="checkbox"/> Yes <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> No
Bloating	<input type="checkbox"/> Yes <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> No
Weight change	<input type="checkbox"/> Yes <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> No
Acne	<input type="checkbox"/> Yes <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> No
Other Please specify: .....	<input type="checkbox"/> Yes <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> No
<b>4. Implant adherence</b>	

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Have you had your implant removed in the last 30 days?	<input type="checkbox"/> Yes; date of removal: DD/MMM/YYYY <input type="checkbox"/> No
<b>5. Healthcare resource use</b>	
<b>5a.</b> 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)	<input type="checkbox"/> Yes- please complete section <b>5b.</b> <input type="checkbox"/> No – please move to section <b>5c.</b>
<b>5b.</b> If yes – NHS service contacted about problem bleeding or study treatment:	
GP appointment	<input type="checkbox"/> Yes – face-to- face (no of visits: _____) <input type="checkbox"/> Yes – virtual (phone call/ video) (no of visits: _____) <input type="checkbox"/> No
Nurse (GP Surgery) appointment	<input type="checkbox"/> Yes – face-to- face (no of visits: _____) <input type="checkbox"/> Yes – virtual (phone call/ video) (no of visits: _____) <input type="checkbox"/> No
Specialist sexual health clinic appointment (e.g. GUM clinic)	<input type="checkbox"/> Yes – face-to- face (no of visits: _____) <input type="checkbox"/> Yes – virtual (phone call/ video) (no of visits: _____) <input type="checkbox"/> No
Women’s Health Hubs	<input type="checkbox"/> Yes – face-to- face (no of visits: _____) <input type="checkbox"/> Yes – virtual (phone call/ video) (no of visits: _____) <input type="checkbox"/> No
Community gynaecology clinic	<input type="checkbox"/> Yes – face-to- face (no of visits: _____) <input type="checkbox"/> Yes – virtual (phone call/ video) (no of visits: _____) <input type="checkbox"/> No
NHS outpatient appointment (other than a specialist sexual health clinic/GUM clinic /community gynaecology or women’s health hub)	<input type="checkbox"/> Yes – face-to- face (no of visits: _____) <input type="checkbox"/> Yes – virtual (phone call/ video) (no of visits: _____) <input type="checkbox"/> No
NHS walk in centre	<input type="checkbox"/> Yes – face-to- face (no of visits: _____) <input type="checkbox"/> Yes – virtual (phone call/ video) (no of visits: _____) <input type="checkbox"/> No

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NHS 111	<input type="checkbox"/> Yes – face-to- face (no of visits: _____) <input type="checkbox"/> Yes – virtual (phone call/ video) (no of visits: _____) <input type="checkbox"/> No	
GP out of hours service	<input type="checkbox"/> Yes – face-to- face (no of visits: _____) <input type="checkbox"/> Yes – virtual (phone call/ video) (no of visits: _____) <input type="checkbox"/> No	
Pharmacy	<input type="checkbox"/> Yes – face-to- face (no of visits: _____) <input type="checkbox"/> Yes – virtual (phone call/ video) (no of visits: _____) <input type="checkbox"/> No	
A & E Department	<input type="checkbox"/> Yes (no of visits: _____) <input type="checkbox"/> No	
Other Please specify: .....	<input type="checkbox"/> Yes (no of visits: _____) <input type="checkbox"/> No	
<b>5c.</b> 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)?		
<input type="checkbox"/> Yes-please complete question <b>5d</b> <input type="checkbox"/> No-please move to question <b>6</b>		
<b>5d.</b> 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	<input type="checkbox"/> Yes	
Menstrual cup(s)	<input type="checkbox"/> Yes	
Underwear	<input type="checkbox"/> Yes	
Painkillers	<input type="checkbox"/> Yes	
Iron supplements	<input type="checkbox"/> Yes	
Other 1- please write in		
Other 2- please write in		

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

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

Participant initials:

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Participant ID:

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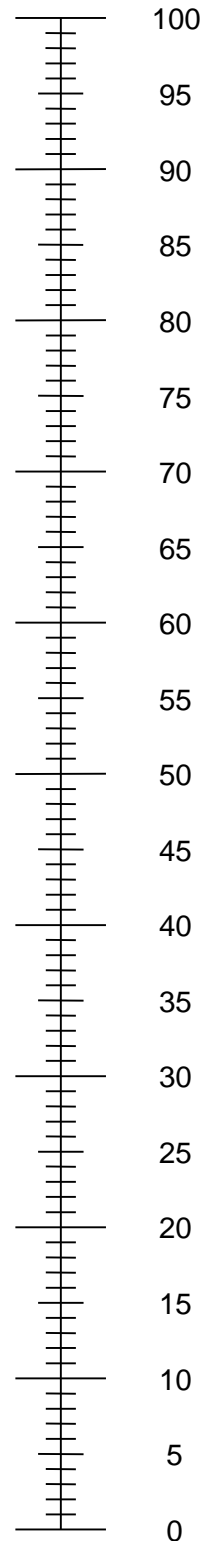
<b>MOBILITY</b>	
I have no problems in walking about	
I have slight problems in walking about	
I have moderate problems in walking about	
I have severe problems in walking about	
I am unable to walk about	
<b>SELF-CARE</b>	
I have no problems washing or dressing myself	
I have slight problems washing 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	
<b>USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)</b>	
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	
<b>PAIN / DISCOMFORT</b>	
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	
<b>ANXIETY / DEPRESSION</b>	
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	

Participant initials:

Participant ID:

- 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.

The best health  
you can imagine



YOUR HEALTH TODAY =

The worst health  
you can imagine

Participant initials:

Participant ID:

### 7. 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 <b>all</b> areas of my life          | <input type="checkbox"/> | 4 |
| I am able to feel settled and secure in <b>many</b> areas of my life         | <input type="checkbox"/> | 3 |
| I am able to feel settled and secure in <b>a few</b> areas of my life        | <input type="checkbox"/> | 2 |
| I am <b>unable</b> to feel settled and secure in <b>any</b> areas of my life | <input type="checkbox"/> | 1 |

#### 2. Love, friendship and support

- |   |                          |   |
|---|--------------------------|---|
| I can have <b>a lot</b> of love, friendship and support       | <input type="checkbox"/> | 4 |
| I can have <b>quite a lot</b> of love, friendship and support | <input type="checkbox"/> | 3 |
| I can have <b>a little</b> love, friendship and support       | <input type="checkbox"/> | 2 |
| I <b>cannot</b> have <b>any</b> love, friendship and support  | <input type="checkbox"/> | 1 |

#### 3. Being independent

- |  |                          |   |
|--|--------------------------|---|
| I am able to be <b>completely</b> independent      | <input type="checkbox"/> | 4 |
| I am able to be independent in <b>many</b> things  | <input type="checkbox"/> | 3 |
| I am able to be independent in <b>a few</b> things | <input type="checkbox"/> | 2 |
| I am <b>unable</b> to be at all independent        | <input type="checkbox"/> | 1 |

#### 4. Achievement and progress

- |   |                          |   |
|---|--------------------------|---|
| I can achieve and progress in <b>all</b> aspects of my life           | <input type="checkbox"/> | 4 |
| I can achieve and progress in <b>many</b> aspects of my life          | <input type="checkbox"/> | 3 |
| I can achieve and progress in <b>a few</b> aspects of my life         | <input type="checkbox"/> | 2 |
| I <b>cannot</b> achieve and progress in <b>any</b> aspects of my life | <input type="checkbox"/> | 1 |

#### 5. Enjoyment and pleasure

- |   |                          |   |
|---|--------------------------|---|
| I can have <b>a lot</b> of enjoyment and pleasure       | <input type="checkbox"/> | 4 |
| I can have <b>quite a lot</b> of enjoyment and pleasure | <input type="checkbox"/> | 3 |
| I can have <b>a little</b> enjoyment and pleasure       | <input type="checkbox"/> | 2 |
| I <b>cannot</b> have <b>any</b> enjoyment and pleasure  | <input type="checkbox"/> | 1 |

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

Participant initials: Participant ID: **8. 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 (1<sup>st</sup> or 2<sup>nd</sup> 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

**8a. Non-steroidal Anti-inflammatory Drugs (NSAIDs) including:**

Ibuprofen	<input type="checkbox"/> Yes Number of days taken in last 30 days: .....
Mefenamic acid	<input type="checkbox"/> Yes Number of days taken in last 30 days: .....
Naproxen	<input type="checkbox"/> Yes Number of days taken in last 30 days: .....
Diclofenac	<input type="checkbox"/> Yes Number of days taken in last 30 days: .....
Celecoxib	<input type="checkbox"/> Yes Number of days taken in last 30 days: .....
Aspirin	<input type="checkbox"/> Yes Number of days taken in last 30 days: .....
Piroxicam	<input type="checkbox"/> Yes Number of days taken in last 30 days: .....
Other NSAID	<input type="checkbox"/> Yes Name..... Number of days taken in last 30 days: .....
<b>8b. Tranexamic acid</b>	<input type="checkbox"/> Yes Number of days taken in last 30 days: .....
<b>8c. Tetracycline antibiotics</b>	
Doxycycline	<input type="checkbox"/> Yes Number of days taken in last 30 days: .....
Lymecycline	<input type="checkbox"/> Yes Number of days taken in last 30 days: .....

Participant initials: Participant ID: 

**8d. Liver enzyme inducing medicines which are inducers of the cytochrome CYP3A4 and CYP450 including: anticonvulsants, antibiotics, antifungals, systemic glucocorticosteroids, antiretrovirals and immunosuppressants**

**Anticonvulsants:**

Phenytoin	<input type="checkbox"/> Yes Number of days taken in last 30 days: .....
Fosphenytoin	<input type="checkbox"/> Yes Number of days taken in last 30 days: .....
Primidone	<input type="checkbox"/> Yes Number of days taken in last 30 days: .....
Rufinamide	<input type="checkbox"/> Yes Number of days taken in last 30 days: .....
Carbamazepine	<input type="checkbox"/> Yes Number of days taken in last 30 days: .....
Eslicarbazepine	<input type="checkbox"/> Yes Number of days taken in last 30 days: .....
Oxcarbazepine	<input type="checkbox"/> Yes Number of days taken in last 30 days: .....
Phenobarbitone	<input type="checkbox"/> Yes Number of days taken in last 30 days: .....
Cenobamate	<input type="checkbox"/> Yes Number of days taken in last 30 days: .....
Topiramate	<input type="checkbox"/> Yes Number of days taken in last 30 days: .....
Lamotrigine	<input type="checkbox"/> Yes Number of days taken in last 30 days: .....

**Antibiotics:**

Rifampicin	<input type="checkbox"/> Yes Number of days taken in last 30 days: .....
Rifabutin	<input type="checkbox"/> Yes Number of days taken in last 30 days: .....

**Antifungals:**

Griseofulvin	<input type="checkbox"/> Yes Number of days taken in last 30 days: .....
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**Systemic glucocorticosteroids:**

Prednisolone	<input type="checkbox"/> Yes Number of days taken in last 30 days: .....
Dexamethasone	<input type="checkbox"/> Yes Number of days taken in last 30 days: .....

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Hydrocortisone	<input type="checkbox"/> Yes Number of days taken in last 30 days: .....
<b>Antiretrovirals:</b>	
Efavirenz	<input type="checkbox"/> Yes Number of days taken in last 30 days: .....
Ritonavir	<input type="checkbox"/> Yes Number of days taken in last 30 days: .....
<b>Immunosuppressants :</b>	
Tacrolimus	<input type="checkbox"/> Yes Number of days taken in last 30 days: .....
<b>Other CYP450 inducers:</b>	
St John's Wort	<input type="checkbox"/> Yes Number of days taken in last 30 days: .....
Modafinil	<input type="checkbox"/> Yes Number of days taken in last 30 days: .....
Bosentan	<input type="checkbox"/> Yes Number of days taken in last 30 days: .....
Aprepitant	<input type="checkbox"/> Yes Number of days taken in last 30 days: .....
Lumacaftor	<input type="checkbox"/> Yes Number of days taken in last 30 days: .....
Statins	<input type="checkbox"/> Yes Number of days taken in last 30 days: .....
Other CYP450 inducers	<input type="checkbox"/> Yes Name..... Number of days taken in last 30 days: .....
<b>Anticoagulants including:</b>	
Warfarin	<input type="checkbox"/> Yes Number of days taken in last 30 days: .....
Low molecular weight heparin (lmwh)	<input type="checkbox"/> Yes Number of days taken in last 30 days: .....
Heparin or direct oral anticoagulants(doacs)	<input type="checkbox"/> Yes Number of days taken in last 30 days: .....
Other anticoagulants	<input type="checkbox"/> Yes Number of days taken in last 30 days: .....
<b>8e. Hormones including:</b>	
Progestogens (other than the etonogestrel implant)	<input type="checkbox"/> Yes Number of days taken in last 30 days: .....
Estrogens	<input type="checkbox"/> Yes Number of days taken in last 30 days: .....

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Testosterone	<input type="checkbox"/> Yes Number of days taken in last 30 days: .....
Other hormones	<input type="checkbox"/> Yes Name..... Number of days taken in last 30 days: .....
<b>8f. Gonadotrophin-releasing hormone (GnRH) analogues including:</b>	
Leuprorelin	<input type="checkbox"/> Yes Number of days taken in last 30 days: .....
Triptorelin	<input type="checkbox"/> Yes Number of days taken in last 30 days: .....
Other GnRH analogues	<input type="checkbox"/> Yes Name..... Number of days taken in last 30 days: .....
<b>8g. Selective progesterone receptor modulators including:</b>	
Ulipristal acetate	<input type="checkbox"/> Yes Number of days taken in last 30 days: .....
<b>8h. GLP-1 agonists including:</b>	
Tirzepatide	<input type="checkbox"/> Yes Number of days taken in last 30 days: .....
Semaglutide	<input type="checkbox"/> Yes Number of days taken in last 30 days: .....
Exenatide	<input type="checkbox"/> Yes Number of days taken in last 30 days: .....
Liraglutide	<input type="checkbox"/> Yes Number of days taken in last 30 days: .....
Dulaglutide	<input type="checkbox"/> Yes Number of days taken in last 30 days: .....
Lixisenatide	<input type="checkbox"/> Yes Number of days taken in last 30 days: .....
Other GLP-1 agonists	<input type="checkbox"/> Yes Name..... Number of days taken in last 30 days: .....
<b>8i. Depot Medroxy-Progesterone Acetate (DMPA)</b>	<input type="checkbox"/> Yes Number of days taken in last 30 days: .....
<b>8j. Tamoxifen</b>	<input type="checkbox"/> Yes Number of days taken in last 30 days: .....
<b>8k. Any other medication taken in the last 30 days not mentioned above</b>	<input type="checkbox"/> Yes - please complete details below <input type="checkbox"/> No
Name..... Number of days taken in last 30 days: .....	Name..... Number of days taken in last 30 days: .....

Participant initials:

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Participant ID:

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Follow up – 60 days

**Thank you for taking the time to complete your DEBI 60 days questionnaire.**

Please return this to us in the prepaid envelope provided.

DEBI Trial

Nottingham Clinical Trials Unit

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<b>Document Title:</b>	60 days Questionnaire
<b>Trial Name:</b>	DEBI
<b>Version No:</b>	Final v2.0
<b>Version Date:</b>	6Jun2025