COLO-PREVENT Pregnancy Notification Form

**Do not send identifiable data or source documents with this report**

**Study Details**

| **Information Requested** | **Response** |
| --- | --- |
| Sponsor reference number | 0834 |
| Study title or Acronym | COLO-PREVENT |
| Centre name or number |  |
| EudraCT number (if a CTIMP) | 2022--000531-23 |
| Chief Investigator | Professor Anne Thomas |
| Principal Investigator |  |
| Participant ID |  |
| Participant Initials |  |

Part 1 – Initial Pregnancy Notification

# Maternal information

| **Information Requested** |  |
| --- | --- |
| Is the individual a research participant or the partner of a male participant? | [ ]  Research Participant[ ]  Partner of a male research participant |
| Year of Birth *(dd/mm/yyyy)* |  |
| Date of Last Menstrual Period *(dd/mm/yyyy)* |  |
| Expected Date of Delivery *(dd/mm/yyyy)* |  |
| Method of contraception |  |
| Contraception used as instructed? (Select one box only) | [ ]  Yes[ ]  No[ ]  Uncertain  |

# Medial History

| **Information Requested** | **Response** |
| --- | --- |
| Are there any known familial disorders, risk factors or conditions that may affect the outcome of the pregnancy. | [ ]  No[ ]  Yes – specify below: |

# Previous Obstetric History

Provide details on all previous pregnancies, including termination or stillbirth

| **Pregnancy Number** | **Gestation (Weeks)** | **Outcome (Including Any Abnormalities)** |
| --- | --- | --- |
| **1** |  |  |
| **2** |  |  |
| **3** |  |  |
| **4** |  |  |
| **5** |  |  |

# Trial medication information

List all trial therapies taken in the 3 months prior to and during pregnancy or mark N/A

| **Name of Drug** | **Daily Dose** | **Route** | **Date Started***(dd/mm/yyyy)* | **Date Stopped***(dd/mm/yyyy)* | **Indication** | **Treatment Start****(week of pregnancy)** | **Treatment Stop****(week of pregnancy)** |
| --- | --- | --- | --- | --- | --- | --- | --- |
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#  Non – trial medication information

List all other (non-trial) medication taken in the 3 months prior to and during pregnancy or mark N/A

| **Name of Drug** | **Daily Dose** | **Route** | **Date Started***(dd/mm/yyyy)* | **Date Stopped***(dd/mm/yyyy)* | **Indication** | **Treatment Start****(week of pregnancy)** | **Treatment Stop****(week of pregnancy)** |
| --- | --- | --- | --- | --- | --- | --- | --- |
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# Prenatal information

| **Information Requested** | **Response** |
| --- | --- |
| Have any specific tests, e.g. amniocentesis, ultrasound, maternal serum AFP, been performed during the pregnancy so far? | [ ]  Yes – complete rows below[ ]  No – move to question 7[ ]  Uncertain |
| Please specify test 1 date and results | Test:Date (dd/mm/yyyy):Result: |
| Please specify test 2 date and results | Test:Date (dd/mm/yyyy):Result: |
| Please specify test 3 date and results | Test:Date (dd/mm/yyyy):Result: |

# Maternal pregnancy associated events

| **Information Requested** | **Response** |
| --- | --- |
| Has the mother experienced any SAEs during the pregnancy? | [ ]  Yes - complete an SAE form and submit to rgosponsor@le.ac.uk immediately[ ]  No[ ]  Uncertain |

# Information source

| **PI details requested** | **Response** |
| --- | --- |
| Name |  |
| Signature\* |  |
| Date |  |
| Contact Number/email |  |

**\*Signatures should be ‘wet ink’ or, if electronic, needs to be an approved/verifiable eSignature e.g. via Adobe Sign or DocuSign. We cannot accept unverifiable electronic signatures on SAE reports for inspection purposes. If Adobe Sign or DocuSign are not available and the form has been completed electronically, please print a copy prior to signing. If it is not possible to obtain a ‘wet ink’ signature please send an unsigned document to** **rgosposnor@le.ac.uk** **and we can facilitate digital signatures via Adobe Sign.**

**Please make a note of when to follow up the pregnancy outcome**

Please return the completed form and copies of any additional anonymised documents to **rgosponsor@le.ac.uk**and copy in **coloprevent@leicester.ac.uk**

Pregnancy Notification Form

PART 2 – Pregnancy Outcome Notification

# Pregnancy outcome

## Termination information

| **Information requested** | **Response** |
| --- | --- |
| Did the pregnancy end with a termination | [ ]  Yes – complete remaining questions in the table[ ]  No – move on to section 1.2 |
| Was the termination therapeutic, planned or spontaneous | [ ]  Therapeutic[ ]  Planned[ ]  Spontaneous |
| What was the date of termination (dd/mm/yyyy) |  |
| Specify the reason for the termination and any abnormalities (if known) |  |

## Delivery Information

| **Information Requested**  | **Response** |
| --- | --- |
| Did the pregnancy end with a delivery | [ ]  Yes – complete remaining questions in the table[ ]  No – move on to section 2 |
| Was the delivery normal, forceps, ventouse or caesarean | [ ]  Normal[ ]  Forceps[ ]  Ventouse[ ]  Caesarean |
| What was the date of delivery (dd/mm/yyyy) |  |
| List any maternal complications or complications related to the birth or mark N/A |  |

# Child outcome

| **Information requested** | **Response** |
| --- | --- |
| What was the outcome of the birth | [ ]  Normal[ ]  Abnormal[ ]  Stillbirth |
| If any abnormalities, please specify and provide dates, if normal or still birth mark as N/A: | [ ]  N/A |
| Gender  | [ ]  Male[ ]  Female |
| Length (cm) |  |
| Weight (kg) |  |
| Head circumference (cm) |  |
| Apgar scores (if known) at | 1 minute5 minutes10 minutes |

# Assessment of seriousness (of pregnancy outcome)

| **Information Requested** | **Response** |
| --- | --- |
| What was the seriousness of the pregnancy outcome | [ ]  Non serious [ ]  Involved prolonged inpatient hospitalisation[ ]  Results in persistent or significant disability /incapacity[ ]  Life-threatening [ ]  Mother diedDate of death (dd/mm/yyyy): [ ]  Stillbirth/neonate died Date of death (dd/mm/yyyy): [ ]  Other seriousness criteria[ ]  Congenital anomaly/birth defect[ ]  Other significant medical event (Please provide details): |

# Assessment of causality (of pregnancy outcome)

| **Information Requested** | **Response** |
| --- | --- |
| Please indicate the relationship to pregnancy outcome to trial medication  | [ ]  Unrelated [ ]  Possibly related\*[ ]  Probably related\*[ ]  Definitely related\* **If any of the fields marked\* have been ticked, the outcome is considered to be RELATED to the study drug.** |

# Additional information

| **Information requested** | **Response** |
| --- | --- |
| Please provide details of any additional information which may be considered relevant to the event |  |

# Information source

| **PI details requested** | **Response** |
| --- | --- |
| Name |  |
| Signature\* |  |
| Date |  |
| Contact Number/email |  |

**\*Signatures should be ‘wet ink’ or, if electronic, needs to be via an approved/verifiable eSignature e.g. Adobe Sign or DocuSign. We cannot accept unverifiable electronic signatures on SAE reports for inspection purposes. If Adobe Sign or DocuSign are not available and the form has been completed electronically, please print a copy prior to signing. If it is not possible to obtain a ‘wet ink’ signature please send an unsigned document to** **rgosposnor@le.ac.uk** **and we can facilitate digital signatures via Adobe Sign.**

**Please make a note of when to follow up the pregnancy outcome**

Please return the completed form and copies of any additional anonymised documents to the Research Governance Office, by email via **rgosponsor@le.ac.uk**