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	Dr Ajay M Verma
Principal Investigator	
Participant ID	
Participant Initials	

Part 1 – Initial Pregnancy Notification

1. 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

2. 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:

3. Previous Obstetric History

Provide details on all previous pregnancies, including termination or stillbirth

Pregnancy Number	Gestation (Weeks)	Outcome (Including Any Abnormalities)
1		
2		

Pregnancy Number	Gestation (Weeks)	Outcome (Including Any Abnormalities)
3		
4		
5		

4. 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)

5. 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)

6. 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:

7. 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

8. 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

1. Pregnancy outcome

1.1 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)	

1.2 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	

2. 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 minute 5 minutes 10 minutes

3. 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 died Date 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):

4. 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.**

5. Additional information

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

6. Information source

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

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