Information Requested	Response
SAE ID *(This is allocated by the Sponsor following the submission of an initial report – to be added to all pages of follow-up and or final reports)*	

Serious Adverse Event – Cover Sheet
(For UoL sponsored clinical trials of investigational medicinal products)

This form must be sent to rgosponsor@le.ac.uk (copy to: coloprevent@leicester.ac.uk) alongside its corresponding SAE reporting form A within 24 hours of the research team becoming aware of the Serious Adverse Event

Information Requested	Response
Study title or Acronym	COLO-PREVENT
Sponsor reference number	0834
Arm of trial	☐ Main Trial (Aspirin OR Aspirin + Metformin)* ☐ Resveratrol Sub-Trial (Resveratrol 5mg OR Resveratrol 250mg OR Placebo)
Drug Company Reference	Catalent trial ref: JPS210068 (Resveratrol Sub-Trial only)
Country of Incidence	United Kingdom
Biological sex	☐ Male ☐ Female ☐ Intersex

** If you are reporting an SAE for a participant randomised to aspirin and metformin you will need to complete the additional drug sheet for the second drug.*

Information Requested	Response
SAE ID *(This is allocated by the Sponsor following the submission of an initial report – to be added to all pages of follow-up and or final reports)*	

Serious Adverse Event - report form A
(For UoL sponsored clinical trials of investigational medicinal products)

This form must be sent to rgosponsor@le.ac.uk within 24 hours of the research team becoming aware of the Serious Adverse Event.
If completing the form by hand please write clearly in block capitals using black ink.
N.B. If the event is a pregnancy, it should be reported on a UoL Pregnancy Notification Form

1. Study Details

Information Requested	Response
Study Sponsor reference number (4-digit reference)	0834
Study title or Acronym	COLO-PREVENT
Centre name or number	
EudraCT number	2022-000531-23
Chief Investigator	Dr Ajay Verma
Principal Investigator	

2. Participant Details

Information Requested	Response
Participant ID	
Participant initials	
Participant **year** of birth	

3. Report / event overview

Information Requested	Response
Type of report *(select one box only)*	☐ Initial ☐ Initial & final ☐ Follow-up Number (Note if this is the first follow-up report enter 1): ☐ Final
Date of report *(dd/mm/yyyy)*	
Title of Serious Adverse Event/Adverse Event of Special Interest	
Is the event an Adverse Event of Special Interest (AESI)? (Please note some studies have specific forms for AESI reporting. Where this is the case, complete the study specific AESI reporting form in place of this SAE reporting form.)	☐ Yes ☐ No
Has the title been updated since the initial report?	☐ Yes - Previous title: ☐ No
Date of onset of symptoms *(dd/mm/yyyy)*	

Information Requested	Response
SAE ID *(This is allocated by the Sponsor following the submission of an initial report – to be added to all pages of follow-up and or final reports)*	

Information Requested	Response
Date event became serious as criteria listed in section 4 *(dd/mm/yyyy)*	
Date study team became aware *(dd/mm/yyyy)*	

4. Serious criteria

(This should not change throughout the course of the SAE, the outcome of the SAE is recorded in Section 10)

Information Requested	Response
Please select the most relevant criteria which categorises this event as serious *(Select one box only)*	☐ Resulted in death ☐ Life threatening ☐ In-patient hospitalisation or prolongation of existing hospitalisation ☐ Persistent or significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other (please specify e.g. AESI):

5. Narrative

Information Requested	Response
Was the participant admitted to hospital?	☐ Yes Hospital admission date *(dd/mm/yyyy)*: Hospital discharge date *(dd/mm/yyyy)*: ☐ No
Describe the event *(please include information on how and when the research team became aware of the event any sequelae and attach any relevant pseudonymised supporting documentation such as medical reports, lab results and discharge summaries. Add continuation pages if needed)*	

Information Requested	Response
SAE ID *(This is allocated by the Sponsor following the submission of an initial report – to be added to all pages of follow-up and or final reports)*	

Information Requested	Response
Please list any treatment given for the SAE	
Please provide any relevant medical history	

5.1 Concomitant medication at time of event

Name of Medication	Indication (s) for Use	Dose	Date of First Administration *(dd/mm/yyyy)*	Date of Last Administration *(dd/mm/yyyy)*

6. Event Severity

Information Requested	Response
What is the severity of the event? *(Select one box only)*	☐ Mild ☐ Moderate ☐ Severe

7. Blinding information

Information Requested	Response
Is the investigational medicinal product (IMP) blinded or unblinded?	☐ Blinded ☐ Unblinded

Information Requested	Response
SAE ID *(This is allocated by the Sponsor following the submission of an initial report – to be added to all pages of follow-up and or final reports)*	

8. Medication Overview

If the study involves more than one IMP, please complete the additional drug sheet.

☐ *Mark this box if an additional drug sheet has been completed* - this should be submitted alongside this SAE report)

Information Requested	Response
Has the participant been administered IMP?	☐ Yes – complete section 8.1 ☐ No – provide reason and move on to section 9 (e.g. participant is still at the screening phase/they are in the standard of care arm):

8.1 Study medication information

Information Requested	Response
Name of IMP	
Indication(s) for use	
Dose (units)	
Route of administration	
Date of first administration	
Date of last administration prior to SAE onset	
Batch/bottle number	

9. Action taken with IMP due to event:

Information Requested	Response
Action taken with IMP due to event	☐ Dose not changed ☐ Temporarily discontinued Date discontinued *(dd/mm/yyyy)*: Date restarted *(dd/mm/yyyy)*: ☐ Permanently discontinued Date permanently discontinued *(dd/mm/yyyy)*: ☐ Dose reduced Provide details: ☐ Unknown at present ☐ Other Provide details: ☐ Not applicable (e.g. participant is still at the screening phase/they are in the standard of care arm) Provide details:

Information Requested	Response
SAE ID *(This is allocated by the Sponsor following the submission of an initial report – to be added to all pages of follow-up and or final reports)*	

10. Causality and Expectedness

****The following section MUST be completed by the Chief/Principal Investigator or other delegated medically qualified Investigator as agreed by the Sponsor****

10.1 Evaluation of causal relationship with IMP

Related – If the causal relationship between the IMP and the SAE is at least a reasonable possibility
Un-related – If there is no causal relationship between the IMP and the SAE

Information Requested	Response
Was the event related to the IMP?	☐ Yes ****Related** – complete the options below and move to section 10.2 ☐ Possibly ☐ Probably ☐ Definitely ☐ No Unrelated - move to section 10.3

10.2 Expectedness - to be completed if the study drug is considered related to the SAE

Information Requested	Response
Was the event expected **as per the information contained within the approved reference safety information?**	☐ Yes- Expected ☐ No - ****Unexpected**
Please detail the RSI Version and date used. *Note this should be the approved RSI at the time that the event occurred.*	

If the event is **related and unexpected it is a Suspected Unexpected Serious Adverse Reaction (SUSAR) and requires expedited reporting. **Inform the Sponsor immediately via rgosponsor@le.ac.uk** (copy to: coloprevent@leicester.ac.uk)

10.3 Relationship to study procedures

Information Requested	Response
Was the event related to a study procedure or intervention other than the IMP?	☐ Yes ☐ No
If yes, is the event expected and what is your assessment of the implications, if any, for the safety of study participants and how will these be addressed? **If no**, mark as not applicable.	

Information Requested	Response
SAE ID *(This is allocated by the Sponsor following the submission of an initial report – to be added to all pages of follow-up and or final reports)*	

11. Protocol Deviation

Information Requested	Response
Was the event related to a protocol deviation?	☐ Yes *(please document on the protocol deviation log and complete a file note)* ☐ No

12. Participant Withdrawal

Information Requested	Response
Was the participant withdrawn from the study as a result of this event?	☐ Yes ☐ No

13. Outcome of the event

Information Requested	Response
What is the outcome of the event? *(Select one box only)*	☐ Resolved Date of resolution *(dd/mm/yyyy)*: ☐ Resolved with Sequelae Details of sequelae: ☐ On-going ☐ Unknown at present ☐ Fatal

13.1 Fatal details

Complete this section if the event resulted in fatality, if not leave blank.

Information Requested	Response
Date of death *(dd/mm/yyyy)*	
Cause of death	
Where was the cause of death obtained from?* *(Select one box only)* * **Redacted** supporting documentation to be supplied with SAE	☐ Working diagnosis ☐ Coroner's inquest ☐ Death certificate

Information Requested	Response
SAE ID *(This is allocated by the Sponsor following the submission of an initial report – to be added to all pages of follow-up and or final reports)*	

14. Reporting persons

***Signatures should be 'wet ink' or, if electronic, this 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 rgosponsor@le.ac.uk and we can facilitate digital signatures via Adobe Sign.**

Information Requested	Reporting person	Principal Investigator/delegated medically qualified individual as agreed by the Sponsor
Name		
Role		
Signature*		
Date		
Contact Number or email		

15. Assessment of relatedness of event

To be completed by the PI or delegated individual who assessed the relatedness of the event to the study procedure or intervention.

I confirm that the causality/expectedness of this event was assessed by myself and I have been delegated this task as per the Delegation of Authority Log. Where the event was considered related to the IMP, the expectedness has been assessed against the approved reference safety information listed above.

Information Requested	Response
Name	
Signature*	

Please return the completed form and copies of any additional anonymised documents to the Research Governance Office, by email via rgosponsor@le.ac.uk (copy to: coloprevent@leicester.ac.uk)

Reporting of SUSARs to the Research Ethics Committee and Regulatory Authority for UoL sponsored studies will be undertaken in accordance with Sponsor SOP S-1009 'Processing and reporting of serious adverse events, serious adverse reactions and suspected unexpected serious adverse reactions for all research sponsored by the University of Leicester'.

Reporting and completion of SAEs not involving investigational medicinal products must be undertaken in accordance with SOP S-1009 using reporting form B.