Serious Adverse Event – Cover Sheet

(For UoL sponsored clinical trials of investigational medicinal products)

**This form must be sent to** [**rgosponsor@le.ac.uk**](mailto:rgosponsor@le.ac.uk)**(copy to:** [**coloprevent@leicester.ac.uk**](mailto: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.*

0834\_COLO-PREVENT\_SAE Cover Sheet\_v2.0, 12/04/2023

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**

# 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 | Professor Anne Thomas |
| Principal Investigator |  |

# Participant Details

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

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

# 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): |

# 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)* |  |
| 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)* |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

# Event Severity

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

# Blinding information

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

# 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): |

## 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 |  |

# 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: |

# 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\*\***

* 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 |

## 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**](mailto:rgosponsor@le.ac.uk) (copy to: [coloprevent@leicester.ac.uk](mailto: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. |  |

# 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 |

# Participant Withdrawal

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| Was the participant withdrawn from the study as a result of this event?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

# 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 |

# 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**](mailto: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 |  |  |

# 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](mailto:rgosponsor@le.ac.uk) (copy to: [coloprevent@leicester.ac.uk](mailto: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.