Serious Adverse Events Reporting Form Completion Guidelines

All signed SAE report forms must be sent to the KHP-CTO by either:

- E-mail: jcto.pharmacovigilance@kcl.ac.uk

Ensure that you are completing the latest version of the SAE Reporting form (found at http://www.khpcto.co.uk/SOP/SAE_Reporting.html)

Please direct any enquiries regarding SAEs to the email address at the top of this page.

General Completion Notes

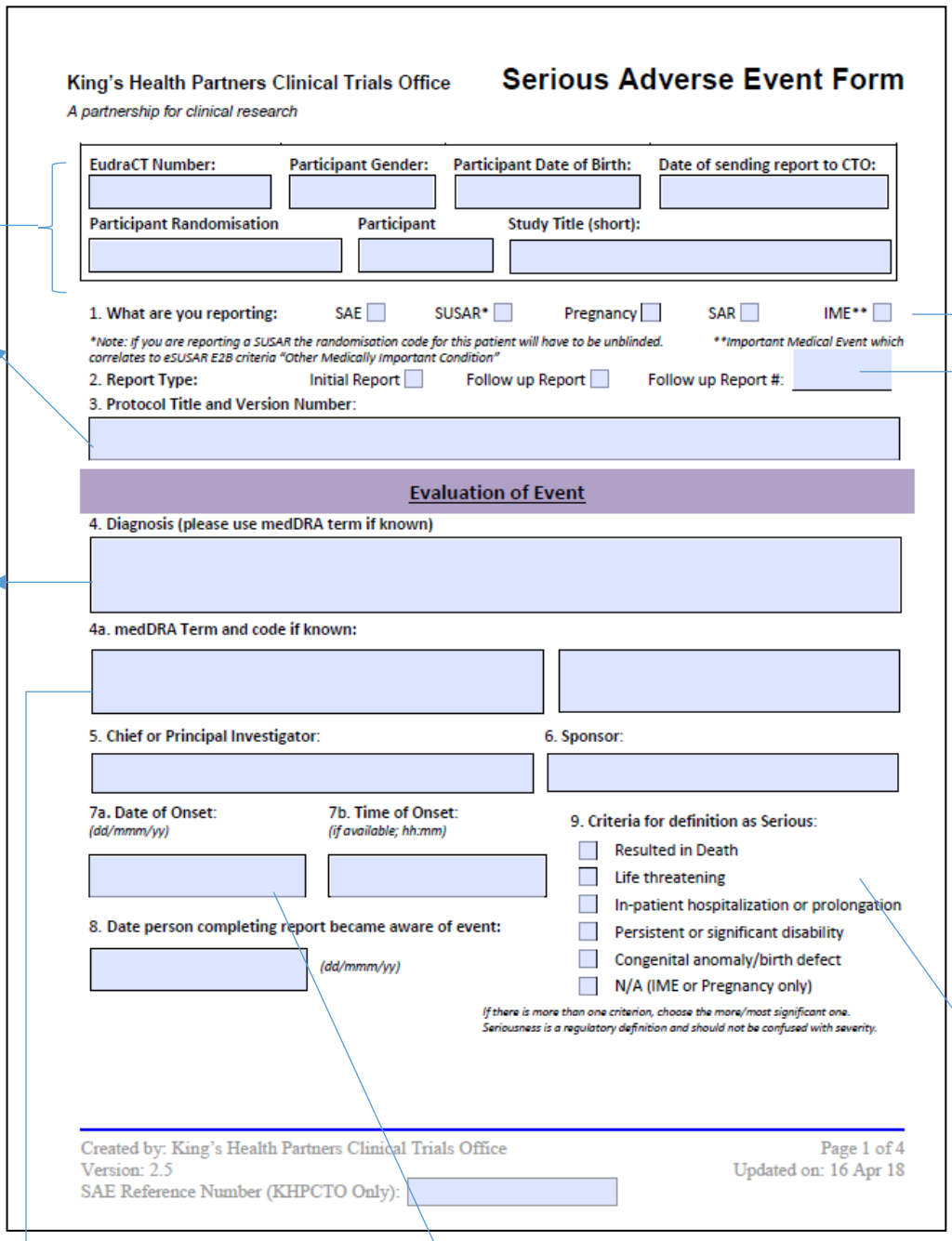
- Avoid leaving blank spaces. "Unknown" may be noted to account for missing data if applicable (i.e. if the event onset time is unknown).
- Please note that we do not collate information together from separate reports to build a complete report. We need the report to include all information such as the event description, con-meds and all signatures before we are able to close the SAE.
- In the case of new hospital admissions/recurrences for the same diagnosis, a new SAE should be reported.

About our SAE Referencing System

- The *SAE Number* begins at SAE001 and increases sequentially for each new SAE that is received.
- The first report form for a particular SAE reported to the KHP-CTO will be classed as the "initial report" for that particular SAE (e.g. SAE001).
- Any further reports we receive relating to the same SAE will be classed as a follow up report regardless of how little or how much information has been amended.

Header:
Complete all header fields. This information will auto-populate on all SAE Form pages once completed.

What you are reporting:
If relatedness to IMP (Q11) is assessed as possibly, likely or definitely, SAR should be ticked. If the SAR is unexpected (Q13) this is then deemed a SUSAR. Any pregnancies should be reported and followed up until childbirth.



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Serious Adverse Event Form

EudraCT Number: | Participant Gender: | Participant Date of Birth: | Date of sending report to CTO:

Participant Randomisation | Participant | Study Title (short):

1. What are you reporting: SAE ☐ SUSAR* ☐ Pregnancy ☐ SAR ☐ IME** ☐

*Note: if you are reporting a SUSAR the randomisation code for this patient will have to be unblinded. **Important Medical Event which correlates to eSUSAR E2B criteria "Other Medically Important Condition"

2. Report Type: Initial Report ☐ Follow up Report ☐ Follow up Report #:

3. Protocol Title and Version Number:

Evaluation of Event

4. Diagnosis (please use medDRA term if known)

4a. medDRA Term and code if known:

5. Chief or Principal Investigator:

6. Sponsor:

7a. Date of Onset: *(dd/mmm/yy)*

7b. Time of Onset: *(if available; hh:mm)*

8. Date person completing report became aware of event: *(dd/mmm/yy)*

9. Criteria for definition as Serious:
- ☐ Resulted in Death
- ☐ Life threatening
- ☐ In-patient hospitalization or prolongation
- ☐ Persistent or significant disability
- ☐ Congenital anomaly/birth defect
- ☐ N/A (IME or Pregnancy only)

If there is more than one criterion, choose the more/most significant one. Seriousness is a regulatory definition and should not be confused with severity.

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Protocol Title:
Please complete with the Study Full Title.

Diagnosis:
Please report diagnosis and not symptoms (these may be added to Q10). In the case of death, please note that this is not an event but an outcome and the cause of death should be reported as the event.

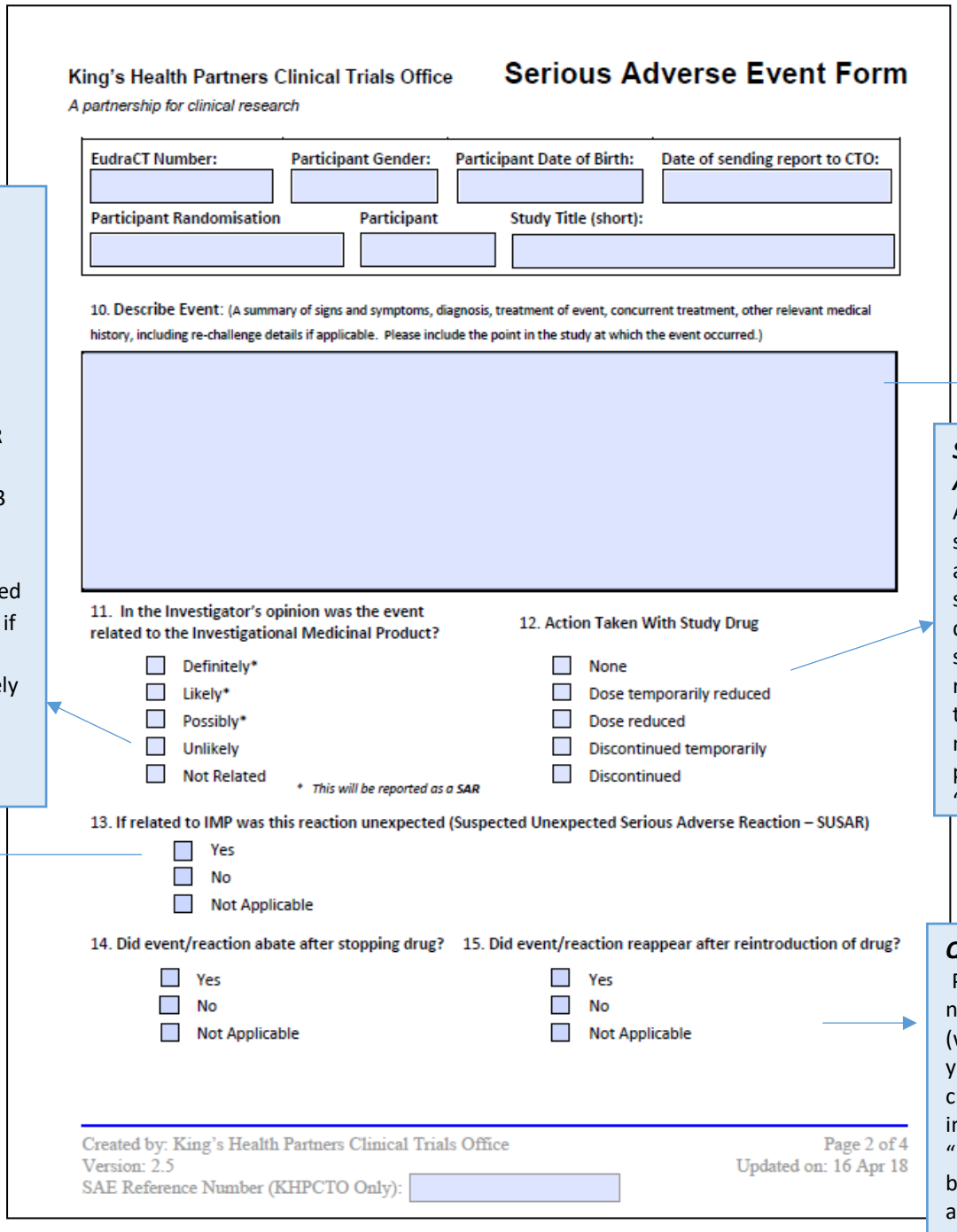
Report Type:
The first time the event is reported will always count as an initial report. Any follow up information (including signatures) will be a considered a follow up report.

SAE Criteria:
If there is more than one criteria, choose the more significant one. Seriousness is a regulatory definition and should not be confused with severity.

medDRA Term and Code:
If you know the medDRA Term and code for the event please enter it here. If unknown please leave blank, this will be assigned by the KHP-CTO following investigator confirmation.

Onset Date:
This is the date that the event became serious. If hospitalisation this will be the date of admission.

Describe Event:
Please provide an account of the event, similar in format to that of a discharge summary. Mention and summarise any symptoms, the diagnosis, any relevant lab data, treatment of the event and other relevant medical notes. If further space is required, you may submit this on a blank page but please include the header details at the top of the page.



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10. Describe Event: (A summary of signs and symptoms, diagnosis, treatment of event, concurrent treatment, other relevant medical history, including re-challenge details if applicable. Please include the point in the study at which the event occurred.)

11. In the Investigator's opinion was the event related to the Investigational Medicinal Product?

- ☐ Definitely*
- ☐ Likely*
- ☐ Possibly*
- ☐ Unlikely
- ☐ Not Related

* *This will be reported as a SAR*

12. Action Taken With Study Drug

- ☐ None
- ☐ Dose temporarily reduced
- ☐ Dose reduced
- ☐ Discontinued temporarily
- ☐ Discontinued

13. If related to IMP was this reaction unexpected (Suspected Unexpected Serious Adverse Reaction – SUSAR)

- ☐ Yes
- ☐ No
- ☐ Not Applicable

14. Did event/reaction abate after stopping drug?

- ☐ Yes
- ☐ No
- ☐ Not Applicable

15. Did event/reaction reappear after reintroduction of drug?

- ☐ Yes
- ☐ No
- ☐ Not Applicable

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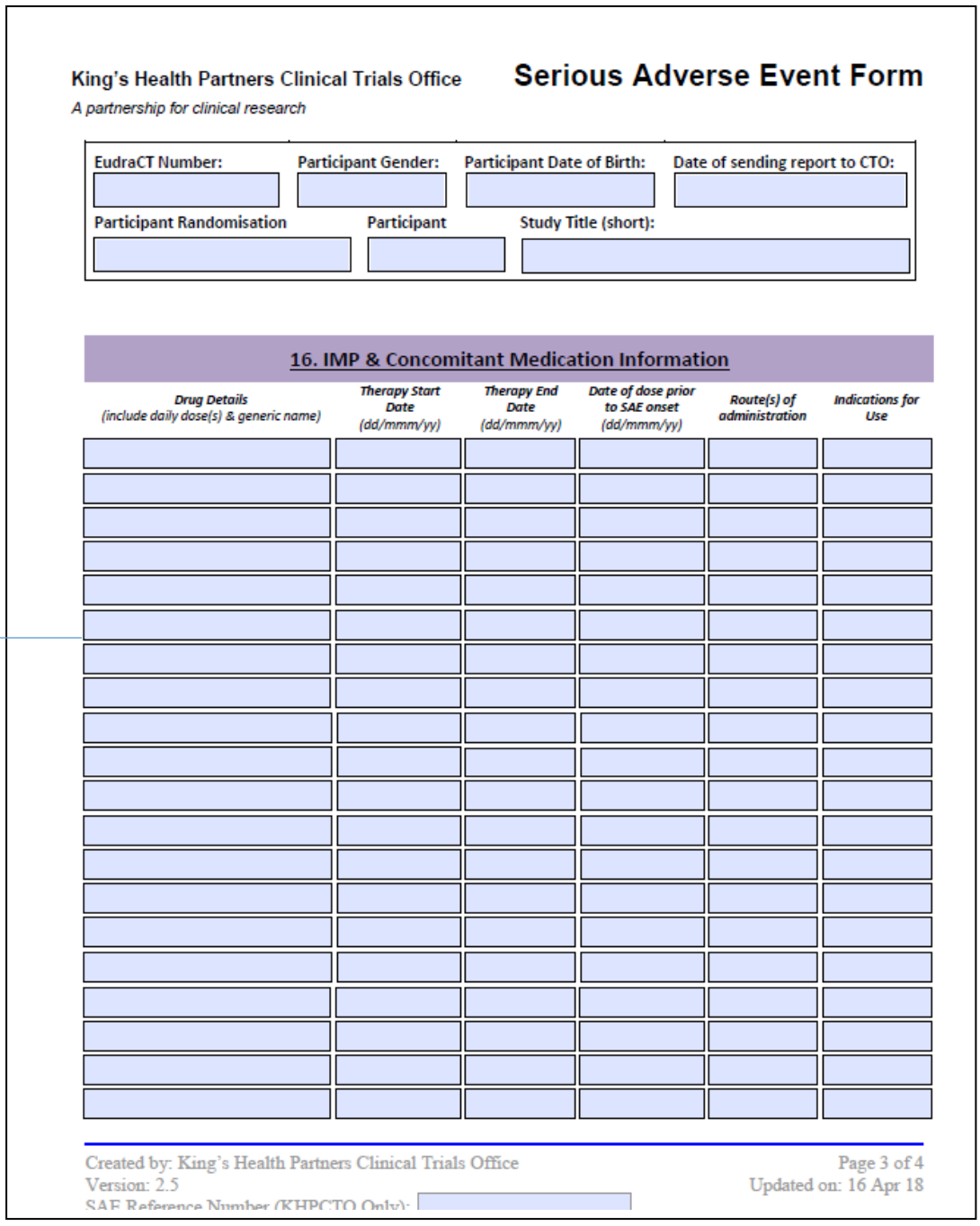
Relatedness to IMP:
If the event is assessed by the investigator as possibly, likely or definitely related, this event is a SAR (Serious Adverse Reaction) and Q13 regarding expectedness should be answered as yes or no. Only if the event is assessed as unlikely or not related can Q13 be left as not applicable.

Study Drug Action:
Any changes to study drug administration such as dose or discontinuation should be reflected here. If there have been no alterations please tick "None".

Q14-15:
Please answer yes or no to these questions (where relevant) if you have confirmed a change in study drug in Q12.
"Not Applicable" can be ticked if Q12 is answered as "None".

Expectedness of event:
The approved IB/SmPC should be consulted to assess expectedness. If the answer to Q11 is answered as *possibly, likely* or *definitely*, this question should <u>always</u> be answered as yes or no.
If you have deemed the event as a SAR and have answered this question "Yes" or have left it blank, this event will then be assessed as a SUSAR. The KHP-CTO will submit the SUSAR to the relevant Competent Authorities within the required timelines.



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16. IMP & Concomitant Medication Information

Drug Details (include daily dose(s) & generic name)	*Therapy Start Date (dd/mmm/yy)*	*Therapy End Date (dd/mmm/yy)*	*Date of dose prior to SAE onset (dd/mmm/yy)*	*Route(s) of administration*	*Indications for Use*

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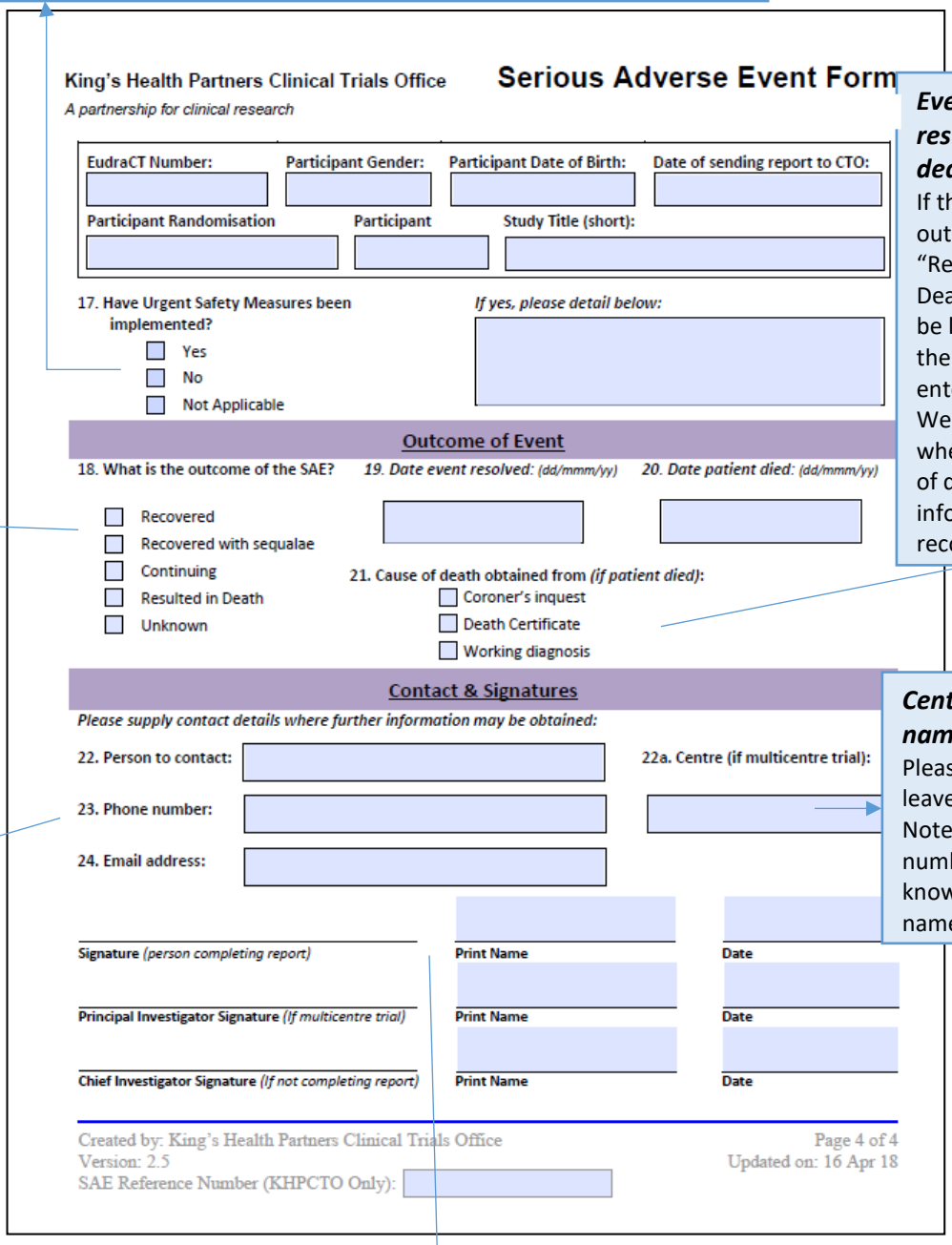
IMP & concomitant medication:

This section must be completed regardless of whether there is a causal relationship with the suspected drug(s). Enter details of IMP(s) involved and any other concomitant medication that the patient may have been taking at the time of event onset.

If there is no concomitant medication or this is unavailable, please state this in the table; *do not leave a blank space*.

Urgent Safety Measures:
These refer to urgent changes to the study procedures (protocol) without prior approval from the regulatory bodies not to urgent clinical safety measures.

Event Resolution:
All SAEs will be followed up until the event is "Recovered", "Recovered with sequelae" or "Death". If you have marked the outcome as "Continuing", we will require a follow up report once the event is resolved. The date entered into Q19 should be the date when the event stopped being serious (i.e. patient discharged from hospital) and should then be followed up as a non-serious AE.



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17. Have Urgent Safety Measures been implemented?
☐ Yes ☐ No ☐ Not Applicable
If yes, please detail below:

Outcome of Event

18. What is the outcome of the SAE? *19. Date event resolved: (dd/mmm/yy)* *20. Date patient died: (dd/mmm/yy)*

☐ Recovered
☐ Recovered with sequalae
☐ Continuing
☐ Resulted in Death
☐ Unknown

21. Cause of death obtained from *(if patient died)*:
☐ Coroner's inquest
☐ Death Certificate
☐ Working diagnosis

Contact & Signatures

Please supply contact details where further information may be obtained:

22. Person to contact: | 22a. Centre (if multicentre trial):
23. Phone number:
24. Email address:

Signature *(person completing report)* | Print Name | Date
Principal Investigator Signature *(If multicentre trial)* | Print Name | Date
Chief Investigator Signature *(If not completing report)* | Print Name | Date

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Events resulting in death:
If the event outcome is "Resulted in Death", Q19 can be left blank and the date of death entered into Q20. We will also need where the cause of death information is recorded.

Contact Details:
<u>Please do not leave blank</u>. We use the contact listed here to send the receipt to. If you complete the form by hand, please write in BLOCK CAPITALS.

Centre name/number
Please do not leave blank. Note site number if known or site name.

Signatures:
The person who completed the form should sign in the top signature row.
<u>Single centre trials</u> – The Chief Investigator (CI) may sign in the CI signature row after review, the Principal Investigator (PI) is not required.
<u>Multicentre trials</u> – PI signature and CI signature are always required unless the SAE report is initially from the CI site (if this is the case, see single centre trials above).
CI signature is required on <u>all</u> final reports before the SAE can be closed.

Sending Reports

via Email

- Please send ALL reports to jcto.pharmacovigilance@kcl.ac.uk
- Make sure the report you are sending has the sender signature on it, you may need to print the report and scan it back in if you have completed it electronically.

Receipts

- Once the KHP-CTO has received your SAE we will then send you a receipt via email within 24 hours/1 business day.
- The "KHP-CTO Reference Number" box refers to the unique SAE number that has been assigned to your particular SAE; please use the "SAE###" part of the reference in future correspondence regarding this SAE.

Update and Review of Reports

- We do not collate information together from separate reports to build a complete report, therefore the latest report must include all information such as the event description, con-meds and all signatures.
- For Multicentre trials, we do not need every report sent for the SAE to be signed by the CI. CI signature is required as a minimum on the initial and final follow up report containing all completed fields. This ensures the CI has had all information available for review. Interim reports may also be signed off as necessary (e.g. if there have been any changes in causality/expectedness).
- If in doubt, please consult your CRA/monitor or send a query to the PV inbox (jcto.pharmacovigilance@kcl.ac.uk).
- **Reports completed electronically**
    - When completing the initial report, you may prefer to save the document to make it easier and quicker to amend if a follow up report is required. Any amendments should be saved with a new file name rather than overwriting the original file.
    - If you are unable to save the report and need to make amendments, you may photocopy the previous report (or the report that requires an update) and make amendments by hand
    - *Please ensure that you initial and date next to every amendment.*

- **Reports completed by hand**
    - Please initial and date next to every amendment

If you have any further questions please direct them to the pharmacovigilance email address.