Serious Adverse Event [SAE] Form Completion Guidelines

All completed SAE report forms must be sent to the KHP-CTO by email:

jcto.pharmacovigilance@kcl.ac.uk

- Ensure that you are completing the latest version of the SAE Reporting form found at https://khpcto.co.uk/SAEs/SAE_Reporting.php.
- Please direct any enquiries regarding SAEs: jcto.pharmacovigilance@kcl.ac.uk

General Completion Notes

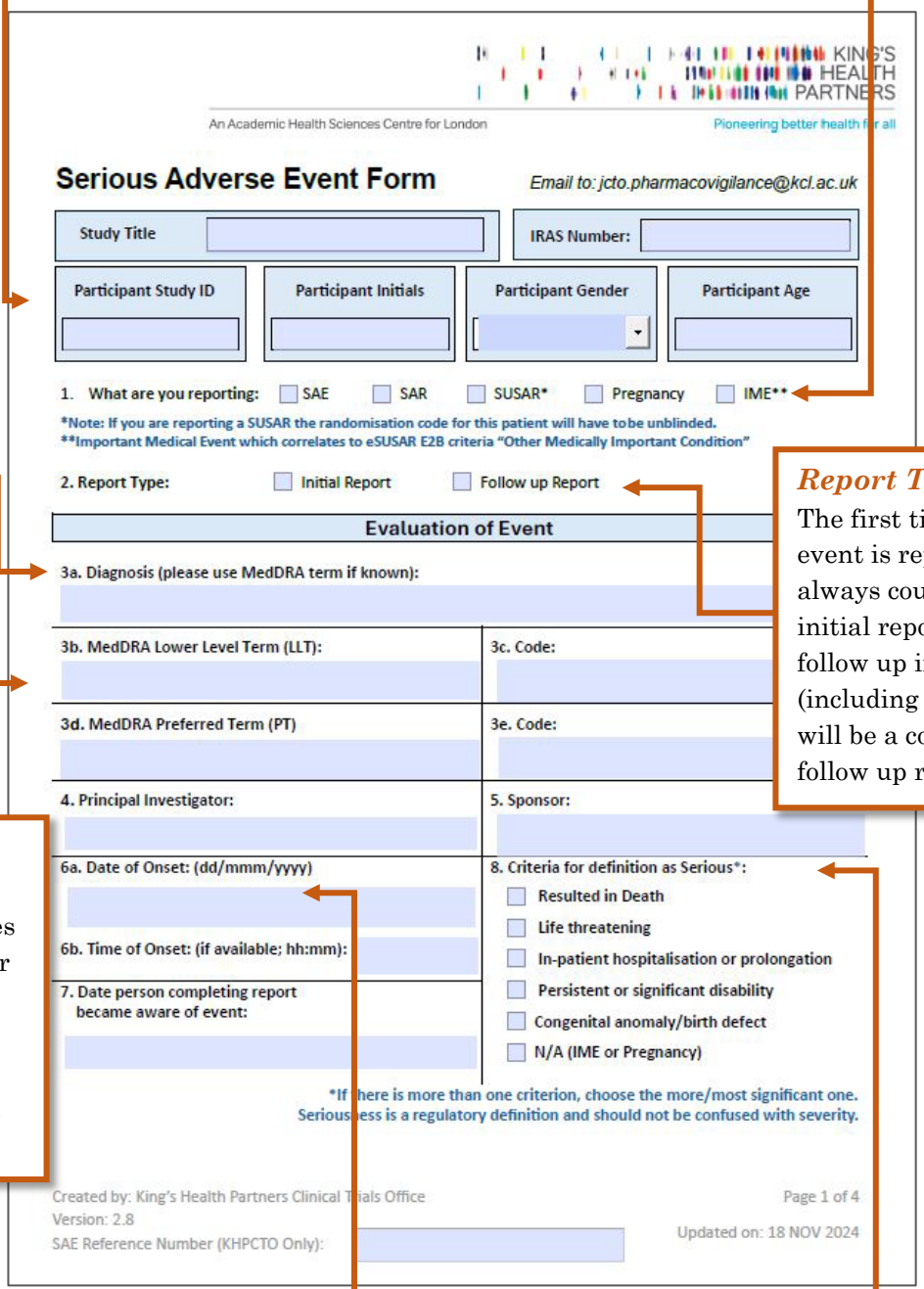
- If you complete the form by hand, please write in **BLOCK CAPITALS**
- Avoid leaving blank spaces. "Unknown" may be noted to account for missing data if applicable (i.e. if the event onset time is unknown).
- Please note that we do not collate information together from separate reports to build a complete report. We need the report to include all information such as the event description, con-meds and all signatures before we can 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 with our KHP-CTO reference number for the study (a four-digit number) and this is followed by the SAE number e.g. 'SAE1'. This number increases sequentially for each new SAE that is received (SAE1, SAE2 etc).
- The first report form for a particular SAE reported to the KHP-CTO will be classed as the "initial report" for that particular SAE.
- 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 (e.g. fu1, fu2 etc).
- Reference numbers are added to each SAE form by the KHP CTO. Site staff are not expected to complete or update this field on the SAE form.

Header: Complete all header fields. This information will auto-populate on all SAE Form pages when the form is completed electronically.

What you are reporting:
If relatedness to IMP **(Q10)** is assessed as possibly, likely, definitely **or unknown**, SAR should be ticked. If the SAR is unexpected this is then deemed a SUSAR. Any pregnancies should be reported and followed up until childbirth.



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Serious Adverse Event Form — *Email to: jcto.pharmacovigilance@kcl.ac.uk*

Study Title | IRAS Number:

Participant Study ID | Participant Initials | Participant Gender | Participant Age

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

Evaluation of Event

3a. Diagnosis (please use MedDRA term if known):

3b. MedDRA Lower Level Term (LLT): | 3c. Code:

3d. MedDRA Preferred Term (PT) | 3e. Code:

4. Principal Investigator: | 5. Sponsor:

6a. Date of Onset: (dd/mmm/yyyy)

6b. Time of Onset: (if available; hh:mm):

7. Date person completing report became aware of event:

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

*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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Diagnosis:
Please report diagnosis and **not symptoms** (these may be added to description **(Q9)**. In the case of death, please note that this is not an event, but an outcome - the cause of death should be reported as the event.

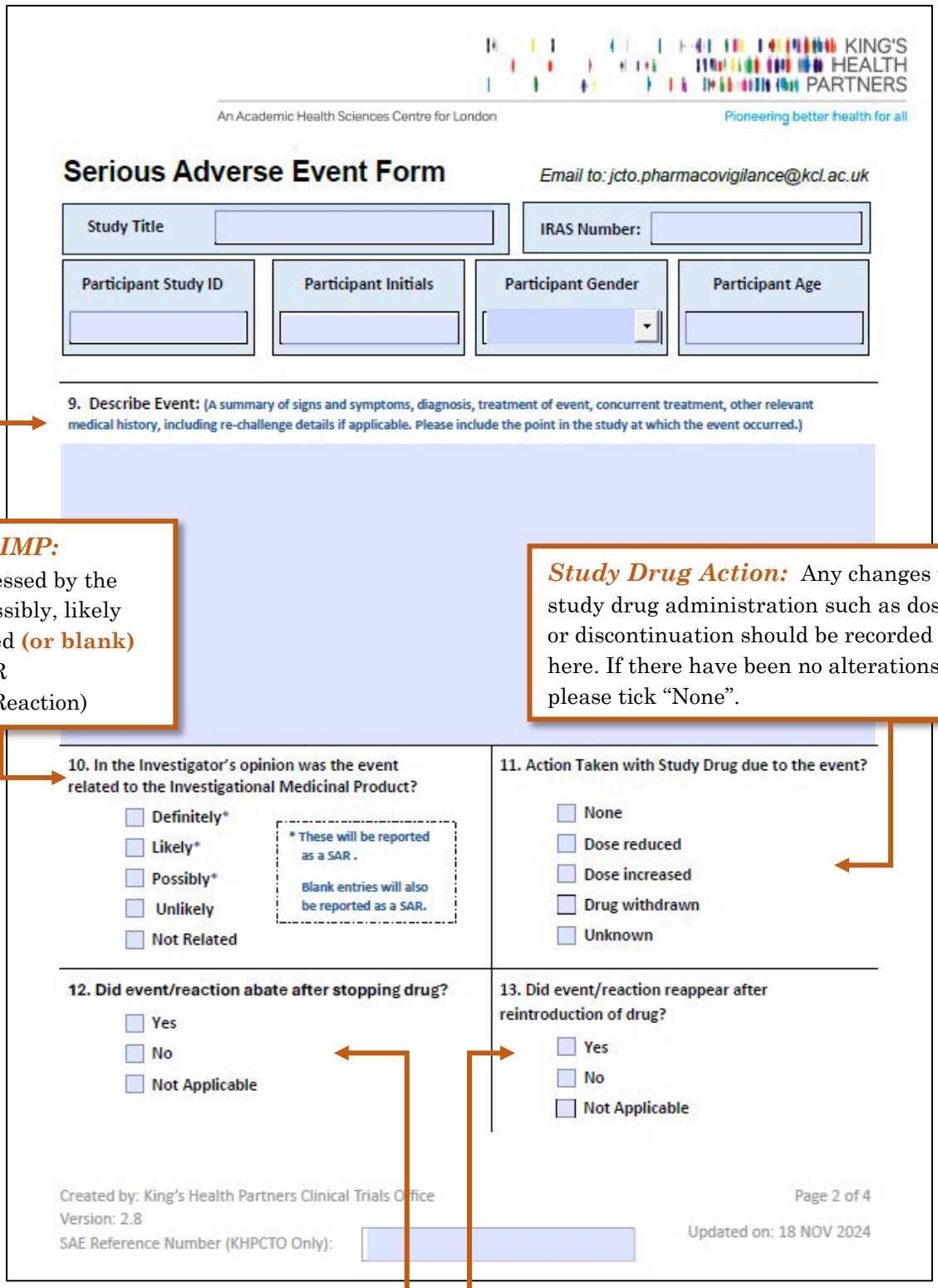
Report Type:
The first time the event is reported will always count as an initial report. Any follow up information (including signatures) will be a considered a follow up report.

MedDRA Terms and Codes: If you know the MedDRA Terms and codes for the event, please enter here. If unknown please leave blank, this will be assigned by the KHP-CTO and confirmed by study investigator.

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

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

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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Study Title		IRAS Number:	
Participant Study ID	Participant Initials	Participant Gender	Participant Age

9. 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.)

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

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

* These will be reported as a SAR.

Blank entries will also be reported as a SAR.

11. Action Taken with Study Drug due to the event?

- ☐ None
- ☐ Dose reduced
- ☐ Dose increased
- ☐ Drug withdrawn
- ☐ Unknown

12. Did event/reaction abate after stopping drug?

- ☐ Yes
- ☐ No
- ☐ Not Applicable

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

- ☐ Yes
- ☐ No
- ☐ Not Applicable

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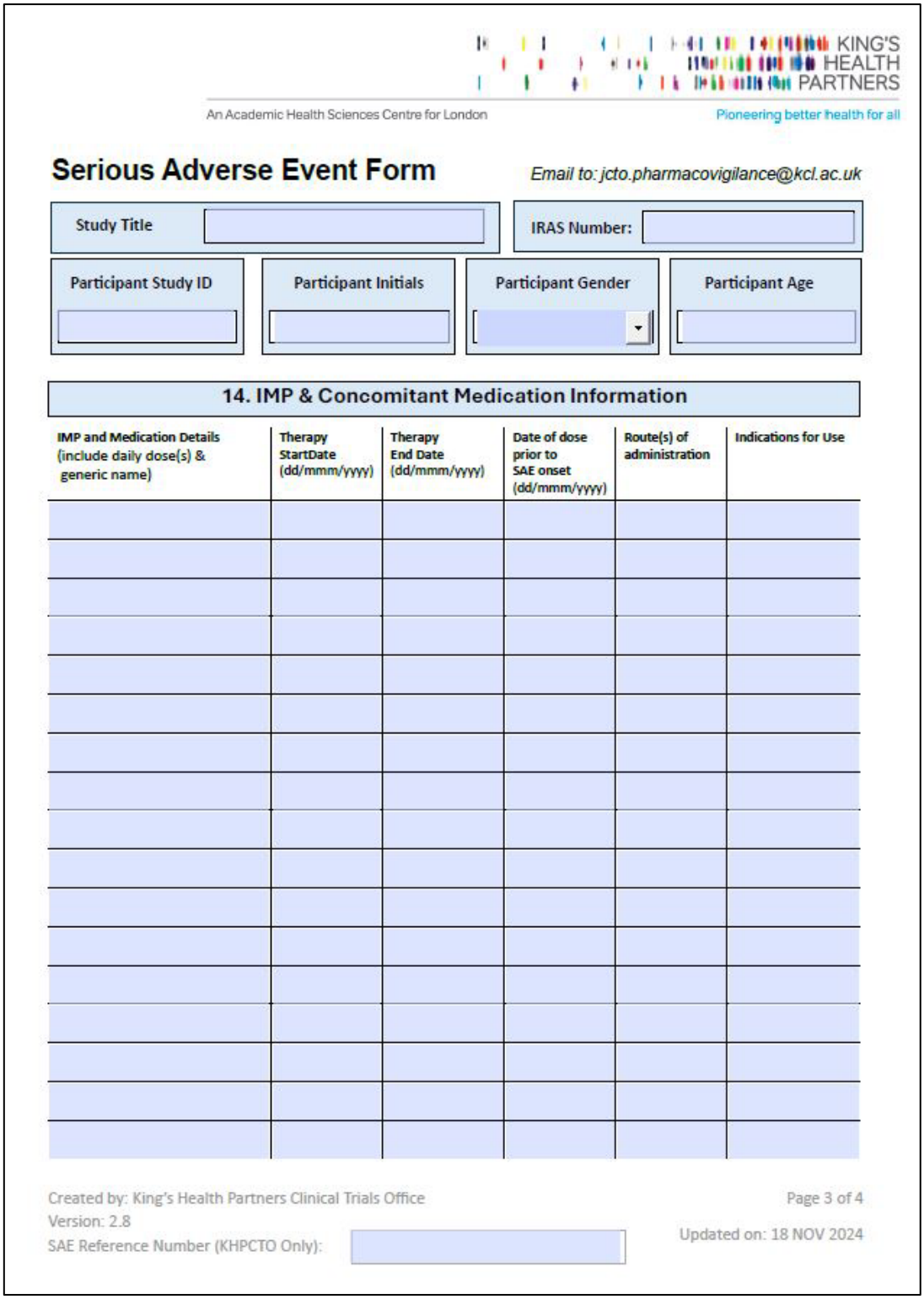
Relatedness to IMP: If the event is assessed by the investigator as possibly, likely or definitely related **(or blank)** this event is a SAR (Serious Adverse Reaction)

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

Q12-13: Please answer yes or no to these questions (where relevant) if you have confirmed a change in study drug in **Q11**. "Not Applicable" can be ticked if **Q11** is answered as "None".



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Study Title		IRAS Number:	

Participant Study ID	Participant Initials	Participant Gender	Participant Age

14. IMP & Concomitant Medication Information

IMP and Medication Details (include daily dose(s) & generic name)	Therapy StartDate (dd/mmm/yyyy)	Therapy End Date (dd/mmm/yyyy)	Date of dose prior to SAE onset (dd/mmm/yyyy)	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 participant 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.**

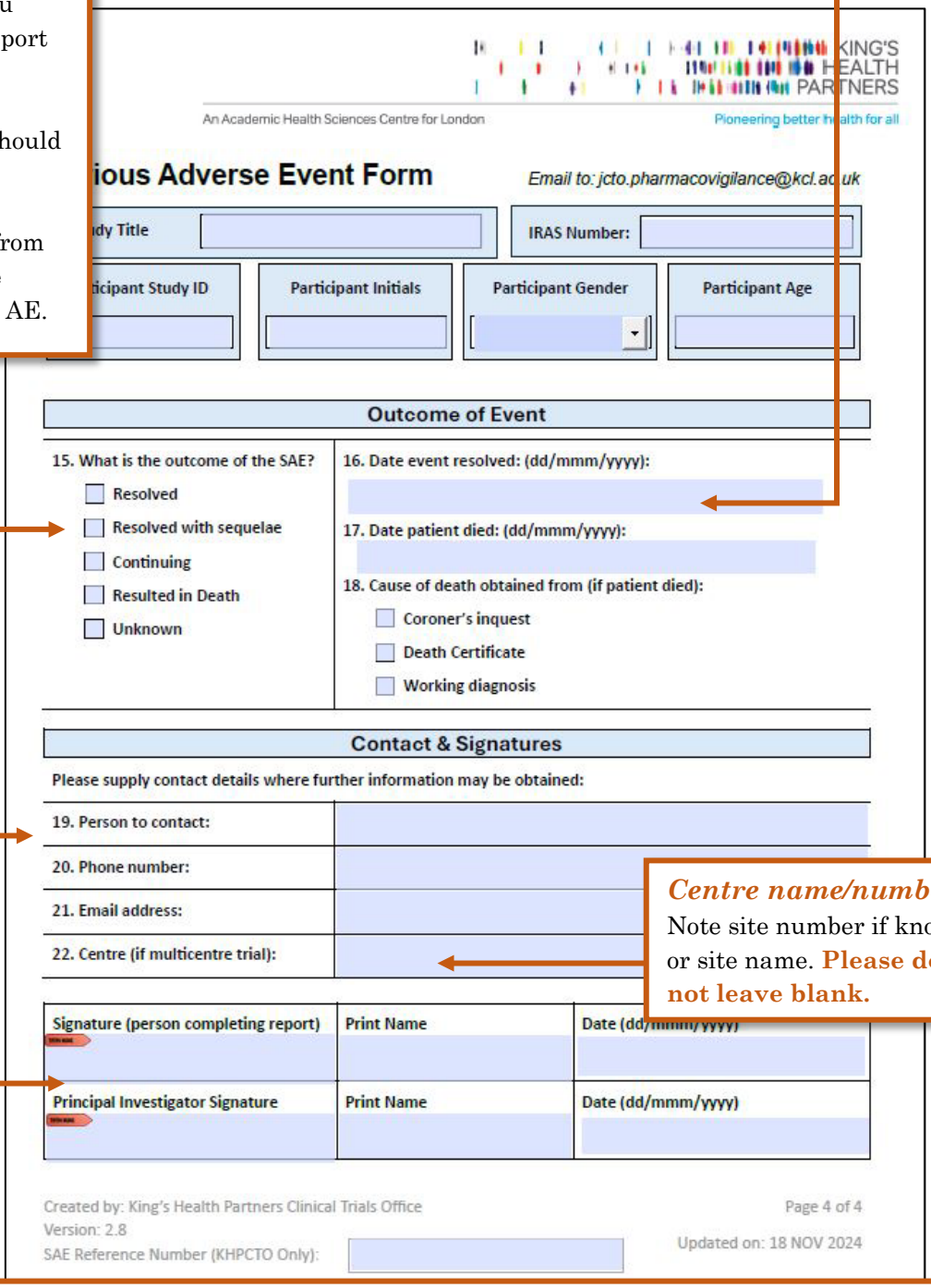
Event Resolution:

All SAEs will be followed up until the event is "Resolved", "Resolved with sequelae" or "Resulted in Death". If you have marked the outcome as "Continuing", you should submit a follow up report once the event is resolved.

The date entered into **Q16** should be the date when the event stopped being serious (i.e. participant discharged from hospital) and should then be followed up as a non-serious AE.

Events resulting in death:

If the event outcome is "Resulted in Death", **Q16** can be left blank, and the date of death entered into **Q17**.



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Outcome of Event

15. What is the outcome of the SAE?
- ☐ Resolved
- ☐ Resolved with sequelae
- ☐ Continuing
- ☐ Resulted in Death
- ☐ Unknown

16. Date event resolved: (dd/mmm/yyyy):

17. Date patient died: (dd/mmm/yyyy):

18. 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:

19. Person to contact:	
20. Phone number:	
21. Email address:	
22. Centre (if multicentre trial):	

Signature (person completing report)	Print Name	Date (dd/mmm/yyyy)
Principal Investigator Signature	Print Name	Date (dd/mmm/yyyy)

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Contact Details:

We use the contact listed here to know where to send the receipt. **Please do not leave blank.**

Centre name/number

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

Signatures:

The person who completed the form should sign in the top signature row.
Single centre trials: If the Chief Investigator (CI) and Principal Investigator (PI) are the same person (as is usually the case), they will sign the PI signature row.

You can send a scanned copy of documents with wet ink signatures or electronically sign using appropriate software (e.g. Adobe Acrobat). **A photograph of a signature alone is not considered an acceptable electronic signature.**

Sending Reports

- 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, sign it and scan it 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 is closed on UK public holidays.
- 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.
- If in doubt, please consult your CRA/monitor or send a query to the PV inbox (jcto.pharmacovigilance@kcl.ac.uk).

Reports completed electronically

- 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** every amendment.

Reports completed by hand

- **Initial and date** next to every amendment.
- Please write in **BLOCK CAPITALS**

If you have any further questions, please send them to the KHP-CTO pharmacovigilance email address:

jcto.pharmacovigilance@kcl.ac.uk