AIR-NET

Adverse Event Recording & Reporting

Adverse Event Definitions

Term	Definition
Adverse Event (AE)	Any untoward medical occurrence in a participant to whom a medicinal product has been administered, including occurrences which are not necessarily caused by or related to that product.
Adverse Reaction (AR)	An untoward and unintended response in a participant to an IMP which is related to any dose administered to that participant. The phrase "response to an IMP" means that a causal relationship between a trial medication and an AE is at least a reasonable possibility, i.e. the relationship cannot be ruled out. All cases judged by either the reporting medically qualified professional or the Sponsor as having a reasonable suspected causal relationship to the trial medication qualify as ARs. It is important to note that this is entirely separate to the known side effects listed in the SmPC. It is specifically a temporal relationship between taking the drug, the half-life, and the time of the event or any valid alternative etiology that would explain the event.
Serious Adverse Event (SAE)	A SAE is any untoward medical occurrence that: results in death is life-threatening requires inpatient hospitalisation or prolongation of existing hospitalisation results in persistent or significant disability/incapacity consists of a congenital anomaly or birth defect Other ‘important medical events’ may also be considered serious if they jeopardise the participant or require an intervention to prevent one of the above consequences. NOTE: The term "life-threatening" in the definition of "serious" refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.

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Serious Adverse Reaction (SAR)	An AE that is both serious and, in the opinion of the reporting Investigator, believed with reasonable probability to be due to one of the trial treatments, based on the information provided.
Suspected Unexpected Serious Adverse Reaction (SUSAR)	A serious adverse reaction, the nature and severity of which is not consistent with the information about the medicinal product in question set out in the reference safety information: in the case of a product with a MA, this could be in the SmPC for that product, so long as it is being used within it's licence. If it is being used off label an assessment of the SmPCs suitability will need to be undertaken. in the case of any other IMP, in the investigator's brochure (IB) relating to the trial in question

Adverse Events as defined in the Protocol

- Worsening of bronchiectasis:
  - Not hospitalised: not AE.
- Worsening of bronchiectasis:
  - Hospitalised: SAE. This should be recorded in Castor AE log, and SAE report submitted.
- All other hospitalisations: SAE
- All other deaths: SAE
- Abnormal laboratory findings:
  - Not requiring medical intervention or medically significant: not AE
  - Requires medical intervention or medically significant: AE
- Worsening of a pre-existing condition:
  - Not clinically significant: not AE
  - Clinically significant: AE

Identifying Adverse Events

- Ask about the occurrence of AEs and hospitalisations at every visit.
    - Worsening of any bronchiectasis symptoms not resulting in hospitalisation should be recorded on the exacerbation form.
    - Worsening of any bronchiectasis symptoms resulting in hospitalisation should be added to the AE log in Castor, and SAE report submitted to PV.

- Review medical records for the occurrence of AEs and hospitalisations at every visit

Exacerbation Form

Participant ID [_] [_] [_] [_] [_] Initials [_] [_] [_]

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Exacerbation recording

Question	Answers
Onset Date	[ ] [ ] [ ] *(dd-mm-yyyy)*
End Date	[ ] [ ] [ ] *(dd-mm-yyyy)*
Assessment of Exacerbation	
Has the participant experienced a deterioration in any of the following key symptoms for at least 48 hours?	
Cough	○ Yes ○ No
Sputum volume and/or consistency	○ Yes ○ No
Sputum purulence	○ Yes ○ No
Breathlessness and/or exercise tolerance	○ Yes ○ No
Fatigue and/or malaise	○ Yes ○ No
Haemoptysis	○ Yes ○ No
How many Symptoms experienced?	
Has the participant experienced 3 or more of the above symptoms?	
If 'Has the participant experienced 3 or more of the above symptoms?' is equal to 'Yes' answer this question:	○ Yes ○ No

Recording Adverse Events(AEs) and Serious Adverse Events (SAEs)

- Details of AEs must be recorded in the medical record for source data verification
- All AEs must be recorded on the AE Log in the eCRF
- AEs must be assessed for severity and relationship to trial medication by the PI
- AEs must be recorded from the time a participant consents to join the trial until the participant's last trial visit
- Any SUSAR, that the investigator becomes aware of, must be reported to the Sponsor irrespective of how long after IMP administration the reaction has occurred
- Unresolved AEs/SAEs at end of trial must be followed up until 30 days after participant's last visit
- SUSARS will be followed until resolution, where a participant agrees to this

Reporting SAEs

- SAEs must be submitted on the online SAE form to the Sponsor Pharmacovigilance Team within 24 hours of becoming aware of the SAE
- If further information is required, this must be provided as soon as available in a follow up report
- Team members delegated SAE reporting will receive PV database training
- The PV database can be accessed here:

https://hicservices.dundee.ac.uk/Pharmacovigilance/