



Value of inhaled treatment with  
aztreonam lysine in bronchiectasis

# Adverse Event Recording and Reporting





## Adverse Event Definitions

Term	Definition
Adverse Event (AE)	<p>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.</p>
Adverse Reaction (AR)	<p>An untoward and unintended response in a participant to an investigational medicinal product (IMP) which is related to any dose administered to that participant.</p> <p>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.</p> <p>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 adverse reactions. Adverse events that may be related to the IMP are listed in the Investigator's Brochure (IB) for each product.</p>



## Adverse Event Definitions (cont.)

Term	Definition
Serious Adverse Event (SAE)	<p>A SAE is any AE that:</p> <ul style="list-style-type: none"><li>• results in death</li><li>• is life-threatening</li><li>• requires inpatient hospitalisation or prolongation of existing hospitalisation</li><li>• results in persistent or significant disability/incapacity</li><li>• consists of a congenital anomaly or birth defect</li></ul> <p>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.</p> <p>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.</p>
Serious Adverse Reaction (SAR)	An adverse event 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 SAR, 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, see section 9.4:



## Adverse Events as defined in the Protocol

- Worsening of bronchiectasis:
  - Not hospitalised: not AE, but is defined as an outcome
- Worsening of bronchiectasis:
  - Hospitalised:
    - Not related to trial medication: AE, not SAE
    - Related to trial medication: SAE
- Hospitalised: SAE unless for elective procedures and for treatment planned prior to randomisation
- Worsening of a pre-existing condition:
  - Not clinically significant: not AE.
  - Clinically significant: AE
- All deaths: SAE



## Identifying Adverse Events

- Ask about the occurrence of AEs and hospitalisations at every visit, in person and telephone
- Review medical records for the occurrence of AEs and hospitalisations at every visit, in person and telephone



## Recording Adverse Events

- 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 by the PI for severity and relationship to trial medication
- 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
- PV database website:

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