**AZTEC**

**Protocol Dosing Error Report Form**

*This form will be required for any under or overdosing of Protocol treatment (excluding dose reductions as a result of clinical requirements).* **OVERDOSES AND UNDERDOSES OF PROTOCOL DRUGS MUST BE REPORTED TO CTR SAFETY TEAM AND TRIAL TEAM WITHIN 24 HOURS OF SITE AWARENESS**

**Completed forms should be sent to:**

[**CTR-Safety@cardiff.ac.uk**](mailto:CTR-Safety@cardiff.ac.uk) **or Fax: 0203 0432 376**

*This CRF is to be completed and returned as soon as the information becomes available*

Participant Initials:  Site Name:

Date of Birth: - - Study ID: AZ

Date of reported dosing error:

Date site made aware of dosing error:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Treatment** | **Treatment day** | **Expected dose**  **(dosage and units found in protocol)** | **Actual dose given**  **(dosage and units found in protocol)** | **Number of days effected by dosing error** |
| AZTEC IMP- Azithromycin/placebo |  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

Was protocol treatment affected as a result of the dosing error? Yes No

If yes please provide details: ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………

Have there been any serious adverse events as a result of the Yes No

dosing error?

If yes, have these been reported to the CTR safety team via an SAE report Yes No

form?

(Where unsure if an event is reportable please contact the CTR safety team for advice)

Where events have been reported as an SAE please confirm SAE report number: …………………………………………………………………………………….……………………………….

Are the baby’s parents aware of the dosing error? Yes No

Form completed by………………………………………………………….. Date:……./……../………

**PI (or delegated medical doctor) comments**

|  |  |
| --- | --- |
| Reason dosing error occurred: |  |
| Corrective actions: |  |
| Preventive actions (to prevent reoccurrence): |  |
| Additional comments: |  |

Confirmation by Principal Investigator (or delegated medical doctor):

Print name:

Signature: ………………………………………………. Date: …………/…………/………………

Review by Chief Investigator (or delegated clinical member of TMG or clinical reviewer):

|  |  |
| --- | --- |
| Impact on participant safety | Major  Minor  No impact |
| Any further actions required? |  |
| Is there a requirement for the safety team to highlight where further SAEs are received for this participant?  If yes, please indicate time period over which this should be undertaken |  |

Confirmation by Chief Investigator (or delegated medical doctor):

Print name:

Signature: ………………………………………………. Date: …………/…………/………………

*Office use only:* Form checked by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: …………/…………/………………

Review by Statistician:

|  |  |
| --- | --- |
| Impact on data integrity | Major  Minor  No impact |
| Any further actions required? |  |

Print name:

Signature: ………………………………………………. Date: …………/…………/………………

If there is a major impact on participant safety or data integrity please pass to the CTR-QA team within 1 working day for further consideration/escalation.

QA review

|  |  |
| --- | --- |
| Any further actions required?  Consider:   * Are the corrective and preventive actions appropriate? * Does the overdose/under dose meet the criteria of a serious breach of GCP/trial protocol? * Addition to the protocol non-compliance log (major impact = violation, minor impact = deviation) |  |

Print name:

Signature: ………………………………………………. Date: …………/…………/………………