Instructions for Completing Protocol ABS-AS-40091 Adverse Event Report Form

General Instructions

The form should be sent via email to the relevant Teva representative (US Pharmacovigilance unit, the email address appears on the AE form). The signed AE form should be filed in by the site indicating the date the form was emailed to a Teva representative.

Dates: All dates are based on a 2-digit day/3-letter month/4-digit year.

- To move from field to field, please use the mouse and not the "enter" button.
- In order to save this form as a template, it should be saved under the following path: c:/program files/Microsoft office/template.
- Each AE report should be opened from the template, saved/print as a separate document.

Section 1 – Study Title

- Complete as applicable.

Section 2 – Patient Details

- Complete as applicable.

Section 3 – Relevant Medical & Family History

- Complete diagnosis or primary symptoms.

Section 4-Patient's SABA Rescue Inhaler

- Complete for patients taking a Teva or non-Teva SABA rescue inhaler. The only Teva SABA rescue inhalers marketed in the US are ProAir HFA and ProAir RespiClick.
- Use additional rows if SABA inhaler discontinued/restarted during follow-up period
- If the AE occurred during the follow up period, please specify also the therapy dates of all the previous trial phases if applicable.
- If additional medications are considered as suspect to the AE, please specify in this section.

Section 5 – Concomitant Medication Information

- Complete generic name of medication (e.g. acetaminophen rather than Tylenol).
- Complete indication (or reason) for use of medication not drug mechanism (e.g. "hypertension" rather than "antihypertensive")
- Complete all medication used to treat the diagnosis and/or associated sign/symptoms

Section 6-Adverse Event and Relationship to Patient's SABA Rescue Inhaler

- Complete only for non-serious AEs related to the patient's Teva rescue inhaler and for all non-asthma SAEs regardless of relationship to rescue inhaler or other medication. A full description should be provided in the narrative section. Use standard medical terminology as far as possible.

- Complete diagnosis (e.g. Acute MI) if known. If it is not possible to provide a diagnosis, the event should be described in terms of signs and symptoms, and suspected etiology(ies) should be addressed in the narrative.
- Complete start date of symptoms (e.g. 'chest pain' which resulted in subject hospitalization) or date of diagnosis if known. Start date should be the date a physician can ascribe the first symptom which supports the diagnosis. (e.g. On 10-Oct-98 pt. has a cough. On 15-Oct-98, chest x-ray = pneumonia. Start date = 10-Oct-98).
- Indicate if the event is non-serious AEs related to the patient's Teva rescue inhaler or a non-asthma SAE. If the event is a non-asthma SAE, further specify the serious criteria:
    1. death
    2. a life-threatening adverse event (i.e., the patient was at immediate risk of death from the event as it occurred); does not include an event that, had it occurred in a more severe form, might have caused death
    3. inpatient hospitalization or prolongation of existing hospitalization, which means that hospital inpatient admission and/or prolongation of hospital stay were required for treatment of an adverse event, or that they occurred as a consequence of the event. Hospitalization for worsening of a preexisting non-asthmatic condition during the patient's participation in this study will be considered a serious adverse event. Hospitalizations scheduled prior to study entry, or for asthma exacerbation symptoms present at the ED visit for which the patient was enrolled or occurring during the 2-week follow-up period, will not be considered serious adverse events.
    4. persistent or significant disability or incapacity (refers to a substantial disruption of one's ability to conduct normal life functions)
    5. a congenital anomaly/birth defect
    6. an important medical event that may not result in death, be life-threatening, or require hospitalization, but may jeopardize the patient and may require medical intervention to prevent one of the outcomes listed in this definition. Examples of such events are intensive treatment in an emergency room or at home for allergic bronchospasm; blood dyscrasias or convulsions that do not result in hospitalization; or the development of drug dependency or drug abuse. NOTE: Any suspected transmission of an infectious agent via a medicinal product is considered an important medical event.
- Indicate Outcome at the time the event is reported. Patients who have had a serious or non-serious adverse event must be followed clinically until all parameters (including laboratory) have either returned to normal, have stabilized or are otherwise explained, or until the patient is referred to the care of a health care professional.

- Designate relationship regarding patient's rescue inhaler to reported event using the following definitions:

  Note: If applicable, more than one serious criterion for an individual AE may be chosen.

  The relationship to the study treatment is characterized as:

TERM	DEFINITION	CLARIFICATION
No Reasonable Possibility (Not Related)	This category applies to those adverse events which, after careful consideration, are clearly due to extraneous causes (disease, environment, etc.) or to those adverse events, which after careful medical consideration at the time they are evaluated, are judged to be unrelated to the test drug.	An adverse experience may be considered No Reasonable Possibility if it is clearly due to extraneous causes or when (must have two): ▪ It does not follow a reasonable temporal sequence from the administration of the test drug. ▪ It could readily have been produced by the subject's clinical state, environmental or toxic factors, or other modes of therapy administered to the subject. ▪ It does not follow a known pattern of response to the test drug. ▪ It does not reappear or worsen when the drug is re-administered.
Reasonable Possibility (Related)	This category applies to those adverse events for which, after careful medical consideration at the time they are evaluated, a connection with the test drug administration cannot be ruled out with certainty or felt with a high degree of certainty to be related to the test drug.	An adverse experience may be considered Reasonable Possibility related if or when (at least two of the following): ▪ It follows a reasonable temporal sequence from administration of the drug. ▪ It could not be reasonably explained by the known characteristics of the subject's clinical state, environmental or toxic factors, or other modes of therapy administered to the subject. ▪ It disappears or decreases on cessation or reduction in dose. There are important exceptions when an adverse event does not disappear upon discontinuation of the drug, yet drug-relatedness clearly exists. ▪ It follows a known pattern

		of response to the test drug.

- For Rescue Inhaler Rechallenge column, answer “If rescue inhaler was stopped and restarted, did the event reappear?”

Section 7. Details for Hospitalization and Death

- If applicable, complete this section.
- Do not include hospitalizations due to acute asthma at the index ED visit or during the 2-week follow-up period; these events are captured on the Visit Form (including ED chart) and Follow-up Form.

Section 8. Case Narrative

- The narrative should summarize all AE relevant clinical and related information. The narrative has to be stand alone and comprehensive. Please try to follow the template.
- Source documents should not be attached to the AE report, but all the relevant information should be summarized in the Narrative.
- Please provide a written report according to the following paragraphs and order:
  - source of report and summary of subject demography
  - summary of medical and drug history
  - the suspect drug(s), timing and conditions surrounding the onset of the reaction(s)
  - the progression of the event(s) and its(their) outcome in the subject
  - if outcome is fatal, relevant details
  - rechallenge information, if applicable
  - reporter’s causal relationship assessment

Section 9-Reporting Source

- Complete as applicable.
- Complete Investigator Name, Investigator Signature and Date