ADVERSE EVENT REPORT AND FOLLOW-UP FORM (PVEX-F02.02) 	**Local Case ID:**
	Receipt Date:
	Signature for entry into effect: **Effective date: 02/09/2015** **Approval date: 24/08/2015**

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1 a. COUNTRY	2. DATE OF BIRTH			2a. AGE (Years)	3. SEX	4-6 REACTION ONSET DATE			8-12 CHECK ALL APPROPIATE TO ADVERSE REACTION
		Day	Month	Year			Day	Month	Year	☐ Patient died ☐ Involved or prolonged inpatient hospitalization ☐ Involved persistent or significant disability or incapacity ☐ Life-threatening ☐ Other significant medical event ☐ Congenital anomaly/birth defect
7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)										

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include active substance)		20. Did reaction abate after stopping the drug? ☐ YES ☐ NO ☐ NA
15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION	21. Did reaction reappear after reintroduction of the drug? ☐ YES ☐ NO ☐ NA
17. INDICATION(S) FOR USE		
18. THERAPY DATES (from/to)	19. THERAPY DURATION	

III. CONCOMITANT DRUG(S) AND MEDICAL HISTORY

22. CONCOMITANT DRUG(S), INDICATIONS AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
23. RELEVANT MEDICAL HISTORY (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

IV. MANUFACTURER INFORMATION

V. REPORTER'S DETAILS

24a. REPORT TYPE ☐ INITIAL ☐ FOLLOW-UP	26. REPORTER'S NAME, QUALIFICATION AND CONTACT DETAILS (INCLUDE ZIP CODE)
24b. REPORT SOURCE ☐ Health professional ☐ Study ☐ Literature ☐ Regulatory Authorities ☐ Patient/Consumer	
25. OTHER IDENTIFICATION Nº:	

VI. GENERAL ADDITIONAL INFORMATION

27. ADVERSE REACTION OUTCOME:

☐ **Recovered/Resolved** ☐ **Recovering/Resolved**
☐ **Recovered/Resolved with Sequelae** ☐ **Not recovered / Not resolved** ☐ **Unknown**

27a. FOR FATAL OUTCOME (, relevant autopsy report or post-mortem findings)

Cause of death:

Autopsy Report: ☐ **Yes (please provide a copy)** ☐ **No**
Post-mortem findings:

28. CAUSALITY ASSESMENT (Causal relationship with the suspect drug)

☐ **RELATED**
☐ **PROBABLY RELATED**
☐ **POSSIBLY RELATED**
☐ **UNLIKELY RELATED**
☐ **NOT RELATED**
☐ **UNKNOWN**

29. END DATE OF THE EVENT:	**29a. ACTION TAKEN WITH SUSPECT DRUG:**
	☐ **Unchanged** ☐ **Dose reduced** ☐ **Dose Increased** ☐ **Discontinued**
	☐ **Interrupted - Date when restarted:** ☐ **Unknown**

30. SUSPECTED MEDICINAL PRODUCT (Mandatory in case of Biological/Biotechnological Products):

- NAME OF THE BIOLOGICAL PRODUCT:

- BATCH NUMBER:

31. OTHER RELEVANT INFORMATION (Relevant family history):

VII. CLINICAL TRIAL ADDITIONAL INFORMATION

32. VALID EudraCT NUMBER (where applicable):	**32a. SPONSOR STUDY NUMBER:**
32b. STUDY NAME:	

33. SEVERITY GRADE:
☐ **Mild** ☐ **Moderate** ☐ **Severe**

34. STUDY PHASE IN WHICH AE STARTED:
☐ **Screening Period** ☐ **Treatment Period** ☐ **Follow-Up Period**

VIII. ADDITIONAL FOLLOW UP QUESTIONS

35. Questions