ADVERSE EVENT REPORTING FORM

A. AER REGISTRATION

1. INITIAL RECEIVED DATE: _____ / _____ / _____ Day Month Year		**2.** REPORT TYPE ☐Initial ☐Follow-up	**3.** LOCAL REFERENCE ID:	**4.** TRACKWISE ID (if applicable):
5. GLOBAL SAFETY DATABASE ID:	**6.** OTHER REFERENCE ID (if applicable):	**7.** CLASSIFICATION: ☐ Spontaneous ☐ Study ☐ Pregnancy ☐ Internet or digital media ☐ Other: _____		**8.** PRIMARY SOURCE COUNTRY:

B. REPORTER´S DETAILS

9. REPORTER TYPE

☐ Physician ☐ Pharmacist ☐ Other Health Care Professional (HCP): _____ ☐ Lawyer ☐ Consumer/patient

☐ Non-Health Care Professional (non-HCP): _____ ☐ Other: _____

10. HAS THE REPORTER GIVEN ITS CONSENT TO PROCESSING PERSONAL DATA[1]? ☐ YES ☐ NO	**11.** REPORTER NAME	
12. REPORTER ADRESS (name of organization if applicable, department, city, country)	**13.** REPORTER EMAIL ADDRESS	**14.** REPORTER PHONE

[1] If NO, questions 11, 12, 13 and 14 are not filled.

C. FOLLOW-UP CONSENT

15. HAS THE REPORTER GIVEN ITS CONSENT TO BE CONTACTED (for the future follow-up to initial case)[2]? ☐ YES ☐ NO	**16.** MAY ZENTIVA CONTACT PATIENT´S PHYSICIAN?[3] ☐ YES ☐ NO	**17.** PHYSICIAN NAME AND CONTACT DETAILS (e-mail address, phone, address)

[2] If NO, questions 16 and 17 are not filled

[3] If NO, questions 17 is not filled

D. PATIENT´S DETAILS

18. PATIENT INITIALS (first, last)	**19**. AGE	**20**. SEX ☐ Female ☐ Male	**21.** AGE GROUP: ☐ Foetus ☐ Neonate (0-27 d) ☐ Infant (28 d-12 m) ☐ Child (1-12 y) ☐ Adolescent (13-18 y) ☐ Adult (19-64 y) ☐ Elderly (65 y and more)

E. ADVERSE EVENT DETAILS (including special situations[4] and pregnancy or breastfeeding)

22. DESCRIBE ADVERSE EVENT (Narrative, including relevant tests/lab data & outcome)	**23.** COUNTRY OF ADVERSE EVENT(S) DETECTION
	24. CHECK ALL APPROPRIATE TO ADVERSE EVENT ☐ Patient died ☐ Involved patient hospitalization ☐ Prolonged patient hospitalization ☐ Involved persistent or significant disability or incapacity ☐ Life-threatening ☐ Congenital anomaly/ birth defect ☐ Other medically important condition[5] ☐ None of mentioned above

25. DETAILS OF ANY TREATMENT RECEIVED FOR THE REPORTED ADVERSE EVENT(S):

26. ADVERSE EVENT	**27.** ONSET DATE	**28.** OUTCOME OF ADVERSE EVENT
		☐ Ongoing ☐ Recovered on: ______________ ☐ Recovered on: ______________and reoccurred on: ______________ ☐ Recovering ☐ Unknown
		☐ Ongoing ☐ Recovered on: ______________ ☐ Recovered on: ______________and reoccurred on: ______________ ☐ Recovering ☐ Unknown
		☐ Ongoing ☐ Recovered on: ______________ ☐ Recovered on: ______________and reoccurred on: ______________ ☐ Recovering ☐ Unknown
		☐ Ongoing ☐ Recovered on: ______________ ☐ Recovered on: ______________and reoccurred on: ______________ ☐ Recovering ☐ Unknown
		☐ Ongoing ☐ Recovered on: ______________ ☐ Recovered on: ______________and reoccurred on: ______________ ☐ Recovering ☐ Unknown

29. HAS THE PATIENT EXPERIENCED THE REPORTED AE(S) IN THE PAST? ☐ YES (describe below) ☐ NO

[4] Overdose, abuse, misuse, off-label use, medication error, lack of drug effect, occupation exposure, suspected or confirmed falsified medicinal product/quality defect of a medicinal product

[5] Only for physician

F. SUSPECT DRUG(S) DETAILS

30. BRAND NAME (including INN, strength, pharmaceutical form, batch number and LOT)	**31.** INDICATION FOR USE	**32.** ROUTE OF ADMINISTRATION	**33.** DAILY DOSE	**34.** THERAPY DATES (from/to)	**35.** THERAPY DURATION	**36.** ACTION TAKEN WITH SUSPECT DRUG
						☐ Treatment ongoing ☐ Treatment discontinued on: ______________ ☐ Treatment discontinued on: ______________and reintroduced on: ______________ ☐ Unknown
						☐ Treatment ongoing ☐ Treatment discontinued on: ______________ ☐ Treatment discontinued on: ______________and reintroduced on: ______________ ☐ Unknown
						☐ Treatment ongoing ☐ Treatment discontinued on: ______________ ☐ Treatment discontinued on: ______________and reintroduced on: ______________ ☐ Unknown
						☐ Treatment ongoing ☐ Treatment discontinued on: ______________ ☐ Treatment discontinued on: ______________and reintroduced on: ______________ ☐ Unknown
						☐ Treatment ongoing ☐ Treatment discontinued on: ______________ ☐ Treatment discontinued on: ______________and reintroduced on: ______________ ☐ Unknown

G. CONCOMITANT DRUG(S) DETAILS (exclude those used to treat adverse event)

37. BRAND NAME (including INN, strength, pharmaceutical form, batch number and LOT)	**38.** INDICATION FOR USE	**39.** ROUTE OF ADMINISTRATION	**40.** DAILY DOSE	**41.** THERAPY DATES (from/to)	**42.** THERAPY DURATION	**43**. NOTES

H. OTHER RELEVANT PATIENT HISTORY (e.g. diagnostics, allergies, risk factors, personal or family medical history if relevant for the adverse event described in this form, pregnancy with last month of period, etc)

44. FROM/TO DATE	**45.** DESCRIPTION

I. LABORATORY DATA

46. TEST DATE	**47.** TEST NAME	**48.** RESULTS	**49**. NOTES

THIS REGISTRATION FORM WAS FILLED BY:	
Name: _	
Contact: _	Department: _ _ _ _ _ _ _ _ _ _ _
Company name: _	Date: _ _ _ _ / _ _ _ _ _ _ _ / _ _ _ _

Please send this form to e-mail address: UKMedInfo@Zentiva.com

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Thank you for taking time to provide this information.