

EVWEB Competency Assessment

Section 2: ICSR Exam Case Second Attempt

This document contains the ICSR Exam Case for your second attempt of Section 2 of the EudraVigilance Competency Assessment.

Please follow carefully the directions below to enter your case:

1. This document contains a CIOMS form that you are required to enter into the EVWEB tool. You will be entering this case as if you are working for a pharmaceutical company called Nobel Pharma.
2. Please complete the ICSR in the EVWEB as you did in the training course using the User Name and Password you were given in the training course.
3. In the field Message number (M.1.4) you must enter your full name.

When you have completed the ICSR message:

1. You must save an electronic copy of the ICSR message in RTF format.
2. Then, send the ICSR message to the EV Training system.
3. Finally, attach the RTF copy to an email and send it to Ms. Malgorzata Durka-Grabowska at the European Medicines Agency (malgorzata.durka-grabowska@ema.europa.eu) specifying the user name you used to enter the case.

1. CIOMS FORM

Suspect Adverse Reaction Report	EMA Mock Case									

I. REACTION INFORMATION

1. PATIENT SH	1a. COUNTRY NL	2. DOB	2a. AGE 72Y	3. SEX M	4. REACTION ONSET	8-12. CHECK ALL ITEMS APPROPRIATE TO ADVERSE REACTION
7+13. DESCRIBE REACTIONS(S) (including relevant tests/lab data)						<input type="checkbox"/> PATIENT DIED <input type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALISATION <input checked="" type="checkbox"/> INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY <input type="checkbox"/> LIFE THREATENING <input type="checkbox"/> CONGENITAL ANOMALY/ BIRTH DEFECT <input type="checkbox"/> MEDICALLY IMPORTANT EVENT
<p>Vertigo Fall Broken hip Deafness</p> <p>A literature report describes a patient admitted to hospital following a fall resulting in a broken hip. On examination by a neurologist, and information comments from a patient health care assistant, mild vertigo with mild deafness were identified. Underlying neurological disease was excluded by MRI brain scan. The author suspected the prolonged use of corticosteroids as a probable cause for deafness and vertigo.</p>						

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG Dexamethasone		20. DID REACTION ABATE AFTER STOPPING DRUG? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO <input type="checkbox"/> NA
15. DAILY DOSE(S) 2-3 Drops (4 times a day)	16. ROUTE(S) OF ADMINISTRATION Topical - Ear	
17. INDICATION(S) FOR USE Otitis externa		21. DID REACTION REAPPEAR AFTER REINTRODUCTION? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
18. THERAPY DATES 05/07/2002 – 17/11/2002	19. THERAPY DURATION	

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION Aspirin 75mg Once Daily Theophylline 20 mg Once Daily Tabs Oral
23. OTHER RELEVANT HISTORY Mild Asthma Ex-smoker

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER Nobel Pharma		Franks E.A, Dexamethasone Causing deafness, Journal of ENT 2003;9:134-136.
24b. MFR CONTROL NO. 20031804-02		
24c. DATE RECEIVED BY MANUFACTURER 30/07/2003	24d. REPORT SOURCE <input type="checkbox"/> STUDY <input checked="" type="checkbox"/> LITERATURE <input type="checkbox"/> HEALTH PROFESSIONAL	
DATE OF THIS REPORT 01/08/2003	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP	