

# EVWEB Competency Assessment

## Section 2: ICSR Exam Case Third Attempt

This document contains the ICSR Exam Case for your third and final 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](mailto:malgorzata.durka-grabowska@ema.europa.eu)) specifying the user name you used to enter the case..

<b>Suspect Adverse Reaction Report</b>	<b>EMA Mock Case</b>									

**I. REACTION INFORMATION**

1. PATIENT BK	1a. COUNTRY US	2. DOB Unk	2a. AGE 72 Years	3. SEX Female	4. REACTION ONSET	8-12. CHECK ALL ITEMS APPROPRIATE TO ADVERSE REACTION  <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
7+13. DESCRIBE REACTIONS(S) (including relevant tests/lab data)  Blurred Vision Macular Oedema Dizziness  Patient presented at hospital with blurred vision and dizziness, ophthalmologic exploration revealed IOP within normal limits and pronounced macular oedema. The therapy was stopped and the patient was discharged with ongoing symptoms.						

**II. SUSPECT DRUG(S) INFORMATION**

14. SUSPECT DRUG Metformin		20. DID REACTION ABATE AFTER STOPPING DRUG?  <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO <input type="checkbox"/> NA
15. DAILY DOSE(S) 500mg Twice a day	16. ROUTE(S) OF ADMINISTRATION Oral	
17. INDICATION(S) FOR USE Type 2 Diabetes		21. DID REACTION REAPPEAR AFTER REINTRODUCTION?  <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
18. THERAPY DATES 22/07/2003 – 22/08/2003	19. THERAPY DURATION 1 Month	

**III. CONCOMITANT DRUG(S) AND HISTORY**

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION Timolol BD 06/02/2000 – Cont. - Glaucoma
23. OTHER RELEVANT HISTORY Glaucoma Arthritis

**IV. MANUFACTURER INFORMATION**

24a. NAME AND ADDRESS OF MANUFACTURER Nobel Pharma	
24b. MFR CONTROL NO. 2948757665HP	
24c. DATE RECEIVED BY MANUFACTURER 25/10/2003	24d. REPORT SOURCE <input type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input checked="" type="checkbox"/> HEALTH PROFESSIONAL
DATE OF THIS REPORT 05/11/2003	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP