ICH E2B

ADVERSE EVENT FORM

M.1.2 Message Format Version	2.1	M.1.3 Message Format Release	2.0	M.1.7b Message Date	12-Aug-2025
M.1.4 Message Number	a0LUc00000JIubt20250813004502				
M.1.5 Message Sender Identifier	LATAMPatientServices		M.1.6 Message Receiver Identifier		LAMMERCK

A.1 Safety Report

A.1.0.1 Safety Report Identifier (Ver.) a0LUc00000JIubt(0)	A.1.1 Primary Source Country
A.1.2 Occur Country	A.1.3b Transmission date 12-Aug-2025
A.1.4 Report Type	A.1.5.1 Serious?
A.1.5.2a Resulted In Death?	A.1.5.2b Life Threatening?
A.1.5.2c Caused/Prolonged Hospitalization?	A.1.5.2d Disabling/ Incapacitating?
A.1.5.2e Congenital anomaly/ birth defect?	A.1.5.2f Other medically important condition?
A.1.6a First received date format 102	A.1.6b First received date 12-Aug-2025
A.1.7b Date of recent info 102	A.1.7b Date of recent info 12-Aug-2025
A.1.8.1 Additional documents?	A.1.8.2 List of documents held by sender
A.1.9 Fulfill expedited criteria?	A.1.10.1 Authority Number
A.1.10.2 Company Number	A.1.11 Other case identifiers in previous transmission?
A.1.13 Case Nullification?	A.1.13.1 Nullification Reason?
A.1.14 Medically confirm?	

A.2 Primary Source

A.2.1.1a Reporter title	A.2.1.1b Reporter given name
A.2.1.1c Reporter middle name	A.2.1.1d Reporter family name
A.2.1.2a Reporter organization	A.2.1.2b Reporter department
A.2.1.2c Reporter street	A.2.1.2 Reporter city
A.2.1.2e Reporter state	A.2.1.2f Reporter post code
A.2.1.3 Reporter country EL SALVADOR(SV)	A.2.1.4 Qualification Consumer or other non health professional(5)
A.2.2 Literature reference(s)	A.2.3.1 Study name
A.2.3.2 Sponsor study no. PSP	A.2.3.3 Observed study type Other Studies(3)

A.3.1 Sender

A.3.1.1 Sender Type	A.3.1.2 Organization
A.3.1.3a Department	A.3.1.3b Title
A.3.1.3c Given name	A.3.1.3d Middle name
A.3.1.3e Family name	A.3.1.4a Street
A.3.1.4b City	A.3.1.4c State
A.3.1.4d Postcode	A.3.1.4e Country code
A.3.1.4f Tel. no.	A.3.1.4g Tel. no. ext.
A.3.1.4h Telephone country code	A.3.1.4i Fax. no.
A.3.1.4j Fax. no. ext.	A.3.1.4k Fax country code

A.3.1.4l Sender’s E-mail Address	
A.3.2 Receiver	
A.3.2.1 Receiver Type	A.3.2.2a Organization
A.3.2.2b Department	A.3.2.2c Title
A.3.2.2d Given name	A.3.2.2e Middle name
A.3.2.2f Family name	A.3.2.3a Street
A.3.2.3b City	A.3.2.3c State
A.3.2.3d Postcode	A.3.2.3e Country
A.3.2.3f Receiver's Telephone Number	A.3.2.3e Receiver's Telephone Number Extension
A.3.2.3h Telephone country code	A.3.2.3i Fax no.
A.3.2.3j Fax no. ext.	A.3.2.3k Fax country code
A.3.2.3l Receiver's E-mail Address	
B.1 Patient	
B.1.1 Patient initial REGC	B.1.1.1a GP medical record no. a0LUc00000JIubt
B.1.1.1b Specialist record no.	B.1.1.1c Hospital record no.
B.1.1.1d Investigation no.	B.1.2.1a Date of birth format 102
B.1.2.1b Date of birth 01-May-1959	B.1.2.2a Onset age
B.1.7.2 Patient medical history text Event Name: E-793907 PDCS_ID: 000435	B.1.2.2b Onset age unit
B.1.2.2.1a Gestation period	B.1.2.2.1b Gestation period unit
B.1.2.3 Patient age group Elderly(6)	B.1.3 Patient weight
B.1.4 Patient height	B.1.5 Sex Male(1)
B.1.6b LMP date	B.3.2 Results of Tests
B.1.7 Patient medical history	
B.1.8 Patient drug therapy	
B.1.9 Patient death	
B.1.9.2 Patient death cause	
B.1.9.4 Patient autopsy	
B.1.9.4a Patient Determine Autopsy MedDRA version	B.1.9.4b Patient Determine Autopsy
B.1.10 Parent	

B.1.10.7 Parent Medical history **B.1.10.8 Parent drug therapy** **B.2 Reaction**	
B.2.i.0 Primary Source Reaction	B.2.i.1.a Reaction MedDRA
B.2.i.1.b Reaction MedDRA LLT	B.2.i.2.a Reaction MedDRA version PT
B.2.i.2.b Reaction MedDRA PT	B.2.i.3 Term highlighted by the reporter?
B.2.i.4a Start date format 102	B.2.i.4b Start date
B.2.i.5a End date format	B.2.i.5b End date
B.2.i.6a Duration	B.2.i.6b Duration unit
B.2.i.7.1a Reaction first time	B.2.i.7.1b Reaction first time
B.2.i.7.2a Reaction last time	B.2.i.7.2b Reaction last time unit
B.2.i.8 Reaction Outcome	
B.3 Test **B.4 Drug**	
B.4.k.1 Drug Characterization Suspect(1)	B.4.k.2.1 Medicinal Product Name Erbitux: ERBITUX
B.4.k.2.3 Obtain Drug Country	B.4.k.3 Drug Batch Number
B.4.k.4.1 Drug Authorization Number	B.4.k.4.2 Drug Authorization Country
B.4.k.4.3 Drug Authorization Holder	B.4.k.5.1 Drug Structure Dosage Number
B.4.k.5.2 Drug Structure Dosage Unit	B.4.k.5.3 Drug Separate Dosage Number
B.4.k.5.4 Drug Interval Dosage Unit Number	B.4.k.5.5 Drug Interval Dosage Definition
B.4.k.5.6 Drug Cumulative Dosage Number	B.4.k.5.7 Drug Cumulative Dosage Unit
B.4.k.6 Drug Dosage Text	B.4.k.7 Drug Dosage Form
B.4.k.8 Drug Administration Route	B.4.k.9 Drug Para Administration
B.4.k.10a Gestation period	B.4.k.10b Gestation period unit
B.4.k.11a Drug Indication MedDRA version	B.4.k.11b Drug Indication
B.4.k.12a Start date format of drug 102	B.4.k.12b Start date of drug 18-Mar-2025
B.4.k.13.1a Drug Start Period	B.4.k.13.1 Drug Start Period Unit
B.4.k.13.2a Drug Last Period	B.4.k.13.2b Drug Last Period Unit
B.4.k.14a Drug end date format	B.4.k.14b Drug end date
B.4.k.15a Duration of drug admin	B.4.k.15b Duration unit of drug admin
B.4.k.16 Action Drug	B.4.k.17.1 Drug recur re-administration
B.4.k.19 Drug Additional	
B.4.k.2.2 Activesubstance **B.4.k.17 Drug recurrence** **B.4.k.18 Drug reaction relatedness**	

B.5 Summary	
B.5.1 Narrative Include Clinical Event Description Esposa de paciente refiere: En 06/2025 estuvo muy mal lo doblaron las aplicaciones del cetuximab y en 07/2025 le bajaron la dosis del cetuximab, no recuerda la dosis actual. Recuperado.	B.5.2 Reporter comment Event Description
B.5.3a Sender Diagnosis MedDRA version	B.5.3b Sender Diagnosis
B.5.4 Sender comment Event Description	

A.1.11 E2B Case References in Previous Transmissions
A.1.12 Linked Cases