Linking the CIOMS I form to the ICH E2B format

The intention of this document is to link fields in **CIOMS I reporting form** with data elements in the **international transfer format ICH E2B** (R2 and R3).

For most of the fields in **CIOMS I** there are corresponding data elements in ICH E2B. However, ICH E2B is a flexible electronic format with several data elements (both as structured information and in free text) intended for data transfer between different databases. **CIOMS I** is a pure reporting form with limited amount of fields (less structured and mostly in free text).
This implies some challenges in the mapping of data between **CIOMS I** and ICH E2B and therefore the table with suggestions in this document should only work as an overview and a guideline.
For example, the free text field *'DESCRIBE REACTION(S)'* in **CIOMS I** can be linked to several structured and free text data elements in ICH E2B.
See page 4-5 in table below.

For more detailed descriptions, please click on the links for **ICH E2B (R2 and R3) guidelines**;

ICH E2B (R2) Individual Case Safety Report (ICSR) Specification and Related Files
http://estri.ich.org/e2br22/index.htm

ICH E2B (R3) Individual Case Safety Report (ICSR) Specification and Related Files
http://estri.ich.org/e2br3/index.htm

SUSPECT ADVERSE REACTION REPORT	

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH Day / Month / Year	2a. AGE Years	3. SEX	4-6 REACTION ONSET Day / Month / Year	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
				F		☐ PATIENT DIED ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION ☐ INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY ☐ LIFE THREATENING

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)		20 DID REACTION ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA
15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION	21. DID REACTION REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA
17. INDICATION(S) FOR USE		
18. THERAPY DATES (from/to)	19. THERAPY DURATION	

III. CONCOMITANT DRUG(S) AND HISTORY

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

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER	
	24b. MFR CONTROL NO.
24c. DATE RECEIVED BY MANUFACTURER	24d. REPORT SOURCE ☐ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL
DATE OF THIS REPORT	25a. REPORT TYPE ☐ INITIAL ☐ FOLLOWUP

CIOMS form	ICH-E2B field (R2)	ICH-E2B field (R3)
I. **REACTION INFORMATION**		
1. **Patient initials** (first, last)	B.1.1 Patient (name or initials)	D.1 Patient (name or initials)
1.a **Country**	A.1.2 Identification of the country where the reaction/event occurred	E.i.9 Identification of the Country Where the Reaction / Event Occurred
2. **Date of birth** (day/month/year)	B.1.2.1 Date of birth	D.2.1 Date of Birth
2.a **Age** (years)	B.1.2.2 Age at time of onset of reaction/event	D.2.2 Age at Time of Onset of Reaction / Event
2. **Sex**	B.1.5 Sex	D.5 Sex
4-6. **Reaction onset** (day/month/year)	B.2.i.4 Date of start of reaction/event	E.i.4 Date of Start of Reaction / Event
7. **Describe reaction(s)**	B.2.i.0 Reaction/event as reported by the primary source B.2.i.8 Outcome of reaction/event at the time of last observation B.4.k.16 Action(s) taken with drug	E.i.1 Reaction / Event as Reported by the Primary Source E.i.7 Outcome of Reaction / Event at the Time of Last Observation G.k.8 Action(s) Taken with Drug

CIOMS form	ICH-E2B field (R2)	ICH-E2B field (R3)
	B.5.1 Case narrative including clinical course, therapeutic measures, outcome and additional relevant information	H.1 Case Narrative Including Clinical Course, Therapeutic Measures, Outcome and Additional Relevant Information
13. (including relevant test lab data)	B.3.2 Results of tests and procedures relevant to the investigation	F.r.3.4 Result Unstructured Data (free text)
8-12. **Check all appropriate to adverse reaction**	A.1.5.1 Serious - *at case level*	-
Patient died	A.1.5.2 Seriousness criteria - *at case level*	E.i.3.2 Seriousness Criteria at Event Level
Involved or prolonged inpatient hospitalization		
Involved persistence or significant disability or incapacity		
Life threatening		
II. **SUSPECT DRUG(S) INFORMATION**	B.4.k.1 Characterization of drug role	G.k.1 Characterisation of Drug Role
14. **Suspect drug(s)** (include generic name)	B.4.k.2 Drug identification B.4.k.3 Batch/lot number	G.k.2 Drug Identification G.k.4.r.7 Batch / Lot Number
15. **Daily dose(s)**	B.4.k.6 Dosage text	G.k.4.r.8 Dosage Text
16. **Route(s) of administration**	B.4.k.8 Route of administration	G.k.4.r.10 Route of Administration
17. **Indication(s) for use**	B.4.k.11 Indication for use in the case	G.k.7 Indication for Use in Case
18. **Therapy dates**	B.4.k.12 Date of start of drug	G.k.4.r.4 Date and Time of Start of Drug

CIOMS form	ICH-E2B field (R2)	ICH-E2B field (R3)
(from/to)	B.4.k.14 Date of last administration	G.k.4.r.5 Date and Time of Last Administration
19. **Therapy duration**	B.4.k.15 Duration of drug administration	G.k.4.r.6 Duration of Drug Administration
20. **Did reaction abate after stopping drug?** ***Yes/No/Na***	B.4.k.16 Action(s) taken with drug	G.k.8 Action(s) Taken with Drug
21. **Did reaction reappear after reintroduction?** ***Yes/No/Na***	B.4.k.17.1 Did reaction recur on readministration?	G.k.9.i.4 Did Reaction Recur on Re-administration?
III. **CONCOMITANT DRUG(S) AND HISTORY**	B.4.k.1 Characterization of drug role	G.k.1 Characterisation of Drug Role
22. **Concomitant drug(s) and dates of administration** (exclude those used to treat reaction)	B.4.k.2 Drug identification B.4.k.12 Date of start of drug B.4.k.14 Date of last administration	G.k.2 Drug Identification G.k.4.r.4 Date and Time of Start of Drug G.k.4.r.5 Date and Time of Last Administration
23. **Other relevant history** (e.g. diagnostics, allergics, pregnancy with last month of period, etc.)	B.1.7 Relevant medical history and concurrent conditions (not including reaction/event)	D.7.2 Text for Relevant Medical History and Concurrent Conditions (not including reaction / event)
IV. **MANUFACTURER INFORMATION**		
24.a **Name and address of manufacturer**	A.1.11.1 Source(s) of the case identifier (e.g. name of the company, name of regulatory agency)	C.1.9.1.r.1 Source(s) of the Case Identifier

CIOMS form	ICH-E2B field (R2)	ICH-E2B field (R3)
24.b **MFR control no.**	A.1.11 Other case identifiers in previous transmissions	C.1.9 Other Case Identifiers
24.c **Date received by manufacturer**	A.1.7b Date of receipt of the most recent information for this report	C.1.5 Date of Most Recent Information for This Report
24.d **Report source** *Study* *Literature* *Health professional*	A.1.4 Type of report A.2.2 Literature reference(s) A.2.1.4 Qualification	C.1.3 Type of Report C.4.r.1 Literature Reference(s) C.2.r.4 Qualification
25.a **Report type** *Initial* *Follow-up*	*Transferring of correct dates (from **24.c**) is based on the CIOMS Report type, i.e. if the report is initial or a follow-up.*	
Date of this report	-	-