

No.	Document title	File name (except version number)	File format	Step 4 in San Diego	Updated		Updated		Updated		Updated		Updated		Updated		Updated		Updated	
				Package 1.00 14 Nov 2012 Version	Package 1.01 12 Apr 2013 Version	Note	Package 1.02 12 Nov 2014 Version	Note	Package 1.03 10 Apr 2015 Version	Note	Package 1.04 10 Nov 2016 Version	Note	Package 1.05 01 June 2017 Version	Note	Package 1.06 16 Nov 2017 Version	Note	Package 1.07 07 June 2018 Version	Note	Package 1.08 22 Jul 2020 Version	Note
1&2	Implementation Guide for Electronic Transmission of Individual Case Safety Reports (ICSRs) E2B(R3) Data Elements and Message Specification	1_ICH_ICSR_Implementation Guide	pdf	5.00	5.01	-	-	-	5.02	Incorporate Q&A and provide additional clarity	-	-	-	-	-	-	-	-	-	-
3	Appendix I (B) to the Implementation Guide for Electronic Transmission of Individual Case Safety Reports (ICSRs) Backwards and Forwards Compatibility Recommendations	3_ICH_ICSR_BFC_Specification	pdf	2.00	-	2.01	Corrections to align with other documents in the IG package	-	2.02	Change reference from M5 to ISO IDMP	-	-	-	-	-	-	-	-	2.03	Editorial corrections made Update scenarios and examples of 5.2.6
	Conversions for E2B(R2)-E2B(R3) compatibility	3_BFC Element Mapping	excel	2.00*	2.01	2.02	Corrections to align with other documents in the IG package	-	-	-	-	-	-	-	-	-	-	-	-	-
4	Appendix I (C) ICH ICSR schema files	4_ICH_ICSR_Schema_Files	htm, xsd	1.00	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5	Appendix I (D) Reference Instances	5_Reference_Instances	xml	3.0	-	3.1	Added "codeSystemVersion"	-	-	-	-	-	-	-	-	-	-	-	-	-
6	Appendix I (E) Example Instances	6_Example_Instances	excel, xml	1.0	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7	Appendix I (F) ICH OID list and ICH code lists	7_E2B Bilingual Code Lists	pdf, xml, xsd, xsl, txt, png	2.3	2.4	2.5	Add 'current flag' to all code lists, correct two labels	2.6	Add leading 0s to "CL14 Route-of-Administration" to make every code 3 digits.	2.7	Add "mg/mL" to CL25 ich-dose-strength-unit. Version number was corrected from 2.6 to 2.7 after the sign-off on 10/Nov/2016. This correction was approved by the Assembly.	2.8	Change UCUM code for decade (from "10a" to "10.a") in the CL26 ich-interval-unit.	2.9	Correct Japanese labels (code 2: from 乳児 to 乳幼児, code 3: from 児童 to 小児) in the CL9 ich-patient-age-group. Correct typo of English label (code 057) and change the current flag (code 046: from y to n) in the CL14 ich-r2-route-of-administration.	-	-	-	-	-
8	Appendix I (G) to the Implementation Guide for Electronic Transmission of Individual Case Safety Reports (ICSRs) Technical Information	8_Technical Information	pdf	1.00	-	1.01	Added "codeSystemVersion", delete unnecessary nullFlavor	-	1.02	Change reference from M5 to ISO IDMP	-	-	-	-	-	-	-	-	-	-
	E2B(R3) Data Element Structure in ICSR messages	8_Reference	excel	1.00	-	1.10	Corrections to align with other documents in the IG package	-	-	-	-	-	-	-	-	-	-	-	-	-
9	Appendix I (H) BFC conversion	9_BFC_conversion	zip (xml, xsd files included)	1.0	-	-	-	-	EU 2.0	This version is updated by EU. Correct errors and add regional requirements.	EU 2.1	This version is updated by EU. Correct errors.	EU 2.5	This version is updated by EU. Added readme file, that includes release notes.	-	-	-	-	-	-
10	User Guide for Use of EDQM Terminologies for Dosage Forms and Routes of Administration	10_User_Guide_Dose_Forms_and_Routes_of_Administration	pdf	-	-	-	-	-	-	-	-	1.0	-	-	-	-	-	1.1	Deleted snapshot mechanism for retrieving EDQM terms; Addition of the method for extraction of the EDQM Standard Terms and codes by using EDQM API  Addition of Mapping table between ICH terms and EDQM Standard terms for route of administration	
11	ICH E2B(R3) Core Data Elements and Business Rules	11_ICH E2B(R3) Core Data Elements and Business Rules	excel	-	-	-	-	-	-	-	-	-	-	1.0	-	-	-	-	-	-

\*: This document was not included in the IG package provided to the Steering Committee in San Diego 2012