

## ICH ICSR BFC Specification

Date	Version	Editor	Page	Section/data elements	Changes
11Nov2014	2.01	TM	15	5.2.1	Revised the wordings: "Same Set of Codes" to "Coded value set".
			15	5.2.1	Added "A" before "E2B(R2) and E2B(R3) expect the same set of codes for the following fields:".
			15, 16	5.2.1	Divided the table into two.
			16	5.2.1	Added the sentence: "B. E2B(R2) and E2B(R3) expect the same terms, however the codes may differ.".
			15	5.2.1	Added an asterisk (*) in D.9.3.
			17	5.2.2	Corrected A.1.13.1 to C.1.11.2.
			22	5.2.8	Corrected B.2.i.1.b to B.2.i.1b.
			25	5.2.12	Deleted "Unknown".
			27	5.3.1	Corrected 8N to 8AN in B.2.i.2.
			27	5.3.1	Corrected 2N to 2AN in ACK: B.1.2.
			29	5.4.1	Corrected 4AN to 8N in F.r.2.2b.
			29	5.4.1	Corrected "filed" to "field".
			29	5.4.1	Corrected "H" to "B.5.1".
			31	5.4.3	Added the wordings: "M5 identifiers have been renamed to ISO IDMP terms and identifiers."
			30	5.4.3	Corrected "D.8.r.3" to "D.8.r.3a".
			31	5.4.3	Corrected "G.k.2.1.2b" to "G.k.2.1.1b".
			32	5.4.5	Deleted space between "100" and "000" in H.5.r.1a.
			34	5.4.7	Corrected "B.1.9.2.b" to "B.1.9.2b".
			34, 35	5.4.8	Corrected "B.1.9.4.b" to "B.1.9.4b".
			35	5.5.1	Added asterisks (*) in C.2.r.1.2, C.2.r.1.3, C.2.r.1.4 and G.k.4.r.9.1.
			37	5.5.2	Corrected "1000" to "100" in B.4.k.19.
			37	5.5.2	Corrected "E.i.1.1" to "E.i.1.1a".
			41	5.6.3	Added MSK and UNK in D.7.1.r.3 and D.10.7.1.r.3.
			41	5.6.3	Corrected "B.1.9.3" to "D.9.3".
			44	5.7.3	Corrected "A.1.10.1" to "C.1.8.1".
			44	5.7.3	Corrected "C.1.8.1" to "A.1.10.2".
			47	5.7.6	Corrected the wording: "true" to "yes, highlighted, serious".
			49	5.7.7	Corrected "50AN" to "50N" in F.r.3.2.
			49	5.7.7	Corrected "F.r.6" to "F.r.3.4".
			49	5.7.7	Deleted "repeatable".
			49	5.7.7	Revised the wordings: "The unique E2B(R2) field B.3.2 should be copied into an additional occurrence of the E2B(R3) fields F.r, where the comments should be copied into the field F.r.6.." to "The unique E2B(R2) field B.3.2 should be copied into the E2B(R3) field F.r.3.4.".
			49	5.7.7	Deleted "(which can be '<', '<=', '>' or '>=')".
			49	5.7.7	Added space between words.
			55, 57	5.7.11	Corrected "see section 5.2.12" to "see section 5.2.11".

Date	Version	Editor	Page	Section/data elements	Changes
			Title	Title	Updated version and date from Version 2.00 14 November 2012 to Version 2.01 11 November 2014.
			-	-	Added a table for Document History
			All	Footer	Updated date from 14 Novemeber 2012 to 11 November 2014.
			1	Table of contents	Updated page number.

## BFC Element Mapping

Date	Version	Editor	Sheet	Data element	Changes
21Jan2013	2.01	AE	C3 Sender D-Patient		Changed R2 to R3 at the title Added title
03Apr2013		AE	The list of ACK data elements	ACK.B.r.7	Added "/Warning" to the element name in
12Apr2013		AE	Readme		Changed R2B(R3) to E2B(R3) at the title
			Ei-Reaction	E.i.7	Changed the cell's background color in Column D and G.
			Ei-Reaction	E.i.7	Revised the wordings in Column I and J: "Same 6 values: okay" to "See in "COD" tab".
			G-Drug	G.k.8	Changed the cell's background color in Column D and G.
			G-Drug	G.k.8	Revised the wordings in Column I and J: "Same 6 values: okay" to "See in "COD" tab".
			F-Test	F.r.2.2a	Corrected 8N to 4AN in F.r.2.2a.
			F-Test	F.r.2.2b	Corrected 4AN to 8N in F.r.2.2b.
			F-Test	F.r.3.2	Corrected "50AN" to "50N".
			F-Test	F.r.6	Removed the wordings; "each occurrence of".
			COD	D.7.1.r.3	Added UNK in R3 field.
			COD	D.10.7.1.r.3	Added UNK in R3 field.
			COD	B.2.i.8	Added codes in Column D.
			COD	E.i.7	Added codes in Column G.
					Revised the wordings in Column H: "Same 6 values: okay" to the followings.
					Same 6 values, different code for "unknown"
			COD	B.2.i.8/E.i.7	Upgrade to R3: - codes 1 to 5, copy as is - code 6 map to 0 Downgrade to R2: - codes 1 to 5, copy as is - code 0 map to 6
			COD	B.4.k.16	Added codes in Column D.
			COD	G.k.8	Added codes in Column G.
11Nov2014	2.02	TM			

Date	Version	Editor	Sheet	Data element	Changes
			COD	B.4.k.16/G.k.8	<p>Revised the wordings in Column H: "Same 6 values: okay" to the followings.</p> <p>Same 6 values, different code for "Unknown" and "Not applicable"</p> <p>Upgrade to R3:</p> <ul style="list-style-type: none"> <li>- codes 1 to 4, copy as is</li> <li>- code 5 map to 0</li> <li>- code 6 map to 9</li> </ul> <p>Downgrade to R2:</p> <ul style="list-style-type: none"> <li>- codes 1 to 4, copy as is</li> <li>- code 0 map to 5</li> <li>- code 9 map to 6</li> </ul>
			NUL	D.1	Added ASKU, NASK and UNK for D.1.
			NUL	D.7.1.r.3/D.10.7.1.r.3	Added UNK in R3 field.
			Document History	-	Added a sheet for Document History.