

Date	Version	Editor	Page	Section/data elements	Changes
20Nov2012		AE	12	copy right	Updated copy right statement with ICH secretariat's suggestion
			53	C.1.9.1.r	Added header C.1.9.1.r.1 Source(s) of the Case Identifier (repeat as necessary)
			43	N.2	Added space between r and ICH at N.2.RICH ICSR MESSAGE HEADER (MESSAGE WRAPPER) (REPEAT AS NECESSARY)
21Jan2013		AE	45	C.1	Added space between of and the at C.1 IDENTIFICATIONOF THE CASE SAFETY REPORT
			104	E.i.3.2	Moved "more than one can be chosen" from the title of "E.i.3.2 Seriousness Criteria at Event Level" to the explanatory text
			101	E diagram	Added E.i.1.1b to the E diagram
31Jan2013		AE	153, 157	datatypes-base, MCCI_MT200101UV	Revised explanation text for datatypes-base and ACK batch schemas.
12Feb2013		AE		D.9 In Case of Death (Header)	Added space between 9 and I.
				D.9.1Date of Death	Added space between 1 and D.
				D.9.2.r Reported Cause(s) of Death	Colour of numbers changed from red to black.
			142	3.5.1	Clarified the wordings: "types of document files" to "file formats of documents"
			142	3.5.1	Clarified the wordings: "sender transmits an attachment separately" to "sender transmits an attachment later"
			142	3.5.1	Clarified the wordings: "then the attachment is transmitted as a follow-up" to "then the ICSR with attachment is transmitted as a follow-up"
05March2013		AE	142	3.5.2	Removed duplicated sentence: "Attachments should be enclosed in a message with its document file type, captured in either C.1.6.1.r.2 or C.4.r.2. Each attachment has up to 3 properties, and the appropriate value for each property should be provided in a message" to "Each attachment has up to 3 properties, and the appropriate value for each property should be provided in either C.1.6.1.r.2 or C.4.r.2a"
			142	3.5.2	Clarified the wordings: "data format standardised by RFC 2046" to "data type standardised by RFC 2046"
			143	3.5.3	Revised code value and OID in XML snippets.
			144	4	Clarified the wordings: "The message includes a standard" to "The acknowledgement message includes a standard"
			144	4.1	Revised explanation about ACK.
			145	4.2	Clarified the wordings: "in received submission" to "in received ICSR messages"
			147	ACK.M.3	Revised the wordings: "transmission of ICSR batch file" to "transmission of ICH ICSR Acknowledgement batch file"
			148	ACK.A.2	Revised the wordings: "the organisation that submitted the ICH ICSR" to "the organisation that received the ICH ICSR"
			148	ACK.A.3	Clarified the wordings: "on which the transaction being acknowledged" to "on which the ICSR batch being acknowledged"
	5.01		76	D.1.1.1	Revised the wordings: <code>&lt;code code="gpmrn"codeSystem="2.16.840.1.113883.3.989.2.1.1.4"/&gt;</code> to <code>&lt;code code="1"codeSystem="2.16.840.1.113883.3.989.2.1.1.4" displayName="GP"/&gt;</code>
			77	D.1.1.1	Revised the wordings: "The code of 'gpmn' is populated to distinguish from D.1.1.2 to D.1.1.4." to "The code of 'GP' is populated to distinguish from D.1.1.2 to D.1.1.4."
			77	D.1.1.2	Revised the wordings: <code>&lt;code code="specialistMrn"codeSystem="2.16.840.1.113883.3.989.2.1.1.4"/&gt;</code> to <code>&lt;code code="2"codeSystem="2.16.840.1.113883.3.989.2.1.1.4" displayName="Specialist"/&gt;</code>
06March2013		MI	77	D.1.1.2	Revised the wordings: "The code of 'specialistMrn' is populated to distinguish from D.1.1.1, D.1.1.3 and D.1.1.4." to "The code of 'Specialist' is populated to distinguish from D.1.1.1, D.1.1.3 and D.1.1.4."
			77	D.1.1.3	Revised the wordings: <code>&lt;code code="hospitalMrn"codeSystem="2.16.840.1.113883.3.989.2.1.1.4"/&gt;</code> to <code>&lt;code code="3"codeSystem="2.16.840.1.113883.3.989.2.1.1.4" displayName="Hospital Record"/&gt;</code>
			77	D.1.1.3	Revised the wordings: "The code of 'hospitalMrn' is populated to distinguish from D.1.1.1, D.1.1.2 and D.1.1.4." to "The code of 'Hospital Record' is populated to distinguish from D.1.1.1, D.1.1.2 and D.1.1.4."
			78	D.1.1.4	Revised the wordings: <code>&lt;code code="investigation"codeSystem="2.16.840.1.113883.3.989.2.1.1.4"/&gt;</code> to <code>&lt;code code="4"codeSystem="2.16.840.1.113883.3.989.2.1.1.4" displayName="Investigation"/&gt;</code>

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			143	3.5.3	<code code="documentsHeldBySender" codesystem="2.16.840.1.113883.3.989.2.1.1.27"/> to <code code="1" codesystem="2.16.840.1.113883.3.989.2.1.1.27" displayName="documentsHeldBySender"/>
03Apr2013		AE	89	D.8.r.7a	Changed "D.8.r.7a" to "D.8.r.7b" at User guidance.
			55	C.1.11.2	Added "reaction/" before event in the user guidance.
09Apr2013		AE	106	E.i.4	Added "/event" after adverse reaction in the user guidance.
				G.k.4.r.10.1	Changed "pharmaceutical dose form" to "route of administration" in the user guidance.
			41	N.1.1	Data type was changed "11A" to "2N" and value allowed was changed "ichicsr" to "1=ichicsr".
12Apr2013		AE	101	Information box	Colour of numbers changed from red to black.
			All	Footer	Updated date from 14 November 2012 to 12 April 2013.
			3	Table of contents	Updated page numbers and applied 'century' to all texts.
10Nov2016	5.02	AE	Many		Incorporate Q&A and provide additional clarity.
18Jul2025	5.03	AE	Many		Update format, incorporate Q&A and provide additional clarity.