

ICH E2BR3 and R2 – COVID-19 specific guidance for certain elements (complete guidelines for ICH E2B(R2) and E2B(R3) at [ICH-ESTRI](#))

E2B(R3)	E2B(R2)	Description	Guidance for COVID-19 related reporting
C.1.3	A.1.4	Type of report	[1=Spontaneous report], [2=Report from Study]
C.5.2	A.2.3.1	Study name	If applicable <i>NB! This information is searchable in VigiLyze.</i>
C.5.3	A.2.3.2	Sponsor study number	If applicable
C.5.4	A.2.3.3	Study type	If applicable [1=Clinical trials], [2=Individual patient use (e.g. ‘compassionate use’ or ‘named patient basis’)], [3=Other studies (e.g. intensive monitoring)]
D.7	B.1.7	Relevant medical history and concurrent conditions	Use this section to capture e.g. co-existing risk factors and underlying conditions.
D.9.2.r.1b D.9.4.r.1b	B.1.9.2b B.1.9.4b	Cause(s) of death Autopsy-determined cause(s) of death	If applicable, this information is coded using appropriate MedDRA terms, reporter’s original words as free text (Free text in D.9.2.r.2 and D.9.4.r.2 respectively for E2BR3).
E.i.2.1b	B.2.i.1	Reaction/event	The MedDRA LLT most closely corresponding to the reaction/event as reported by the primary source should be selected. <i>NB! Therapeutic response in off label use can also be coded here using MedDRA; terms that may apply are e.g. “off label use”, “therapeutic product ineffective for unapproved indication” or “therapeutic product effective for unapproved indication”</i>
F.r	B.3	Results of Tests and Procedures	Use this section to structure tests and procedures relevant to the investigation of the patient, e.g. positive results to SARS-Cov-2 testing.
G.k.7.r.1	N/A	Indication as reported by primary source (free text)	Indication as described by initial reporter <i>NB! This information is not available in VigiLyze due to R3 to R2 conversion.</i>
G.k.7.r.2b	B.4.k.11b	Indication (coded)	Use appropriate term(s) available in current version of MedDRA ¹ <i>NB! If multiple indications – provide most relevant indication first (e.g. COVID-19). This field is repeatable in E2BR3 but only first indication will be available in VigiLyze due to R3 to R2 conversion.</i>
G.k.10.r	N/A	Additional information on drug (coded)	For E2BR3 it is possible to code e.g. off label use in a structured way [11=Off label use] <i>NB! Available in Narrative section in VigiLyze due to R3 to R2 conversion.</i>
G.k.11	B.4.k.19	Additional information on drug (free text)	Capture any additional information about the given drug in free text, e.g. labelling information with regards to the reaction(s).

¹ For countries that still use ICD terminology in ICSR reporting; WHO has issued Emergency use ICD codes for COVID-19 disease (<https://www.who.int/classifications/icd/COVID-19-coding-icd10.pdf?ua=1>) that can similarly be used to code indication.