

**ICH M1 Points to Consider Working Group and MedDRA MSSO
Communication on Coronavirus**
1 April 2020

The coronavirus (COVID-19) pandemic has prompted an urgent need for a harmonised, standardised approach to coding and reporting the infection as a global health issue. The ICH M1 Points to Consider Working Group and the MedDRA MSSO, with the approval of the MedDRA Management Committee, are issuing this notification for MedDRA users regarding existing and new terms for coronavirus concepts.

At the time of this writing, the MSSO has already added several coronavirus related terms to MedDRA and is in the process of adding more. These English supplemental terms can be viewed in the MSSO's [Web-Based Browser](#) but they will not become part of the official MedDRA release until MedDRA Version 23.1 in September 2020. It is recommended that organisations do the following:

- Until implementation of MedDRA Version 23.1, for verbatim reports of COVID-19 related events, code using the existing and more general terms (two right-hand columns in the table below) available in the current version of MedDRA (23.0). Remember to save the original verbatim text.

The table below provides information on the available and proposed supplemental terms to date. Only PTs are shown for the sake of brevity; the subordinate LLTs and the full hierarchy can be viewed in the Supplemental English view in the Web-Based Browser. The table also provides recommendations for the particular existing MedDRA terms to be used to code the concepts represented by the supplemental PTs until the release of MedDRA Version 23.1.

Supplemental Term	Supplemental Code	Existing Term	Existing Code
PT <i>COVID-19</i>	10084268	LLT <i>Coronavirus infection</i>	10051905
PT <i>SARS-CoV-2 test</i>	10084354	LLT <i>Viral test</i>	10062358
PT <i>SARS-CoV-2 test positive</i>	10084271	LLT <i>Coronavirus test positive</i>	10070255
PT <i>SARS-CoV-2 test negative</i>	10084273	LLT <i>Viral test negative</i>	10062362
PT <i>SARS-CoV-2 immunisation*</i>	TBD	LLT <i>Immunisation</i>	10021430
PT <i>COVID-19 treatment*</i>	TBD	LLT <i>Antiviral treatment</i>	10068724
PT <i>COVID-19 prophylaxis*</i>	TBD	LLT <i>Antiviral prophylaxis</i>	10049087

Supplemental Term	Supplemental Code	Existing Term	Existing Code
PT <i>Exposure to SARS-CoV-2</i> *	TBD	LLT <i>Exposure to communicable disease</i>	10049711
PT <i>Suspected COVID-19</i> *	TBD	LLT <i>Coronavirus infection</i>	10051905

* Proposed PT. Term names subject to change. WHO naming conventions are generally followed.

Please contact the [MSSO Help Desk](#) if you have any questions about this communication or use the online Change Request tool, [WebCR](#), to submit any additional change requests for coronavirus related terms.

This notification will be updated between now and the release of MedDRA Version 23.1 in September as new terms are added to MedDRA.

Thank you for your support in facilitating the exchange of information on this critical global health issue.

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