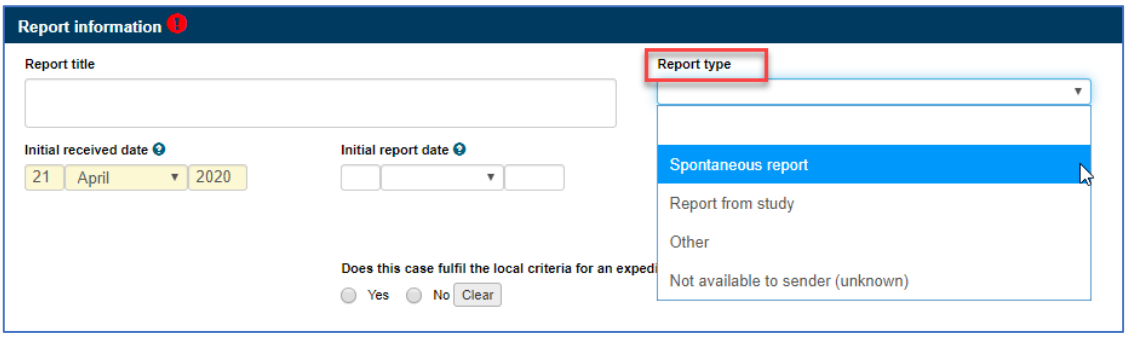
Using VigiFlow for collecting, following-up and sharing safety concerns in connection with treatments for COVID-19

This recommendation applies for countries using VigiFlow as their national drug-safety database. Fields included in this recommendation are commonly used when entering adverse event reports in general. However, we wanted to highlight the importance of a homogenous data collection concerning some fields when it comes to COVID-19 related treatments specifically. In addition, we want to stress the importance of sharing the data with the WHO Programme of international monitoring in a timely manner to build on the knowledge regarding potential safety-issues with COVID-19 treatments. For more details, see the webpage How to capture ICSRs for COVID related treatments.

Report information section

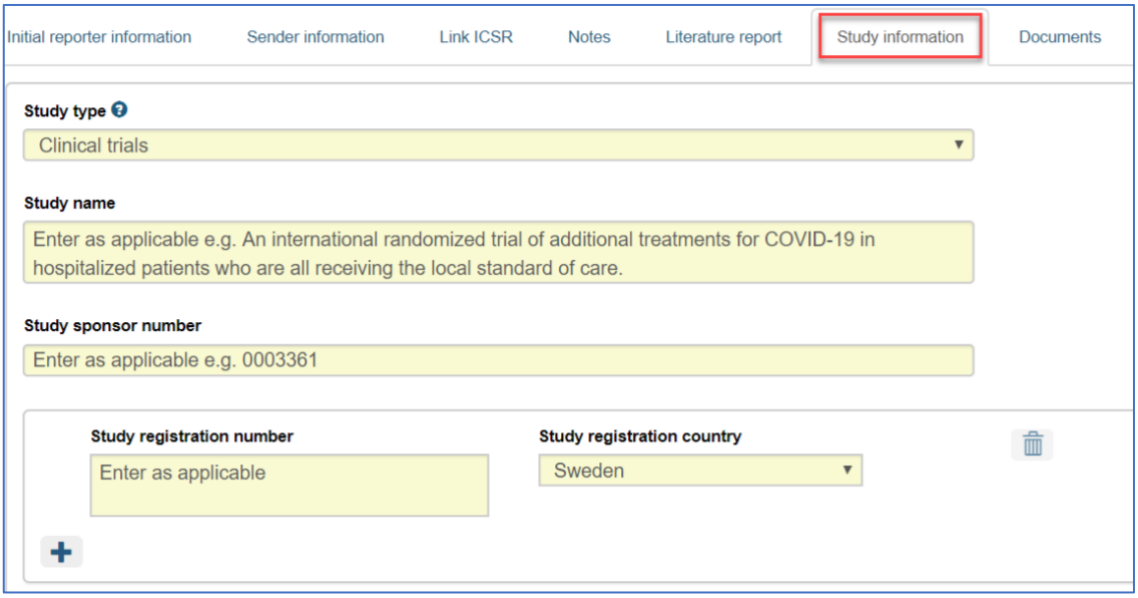
Type of report



Spontaneous: For adverse events collected from the spontaneous reporting system the report type **Spontaneous report** applies

Study: For adverse event reports collected from studies (e.g. WHO SOLIDARITY) the report type **Report from study** applies

Study information tab



Study type: select as applicable (e.g. Clinical trials)

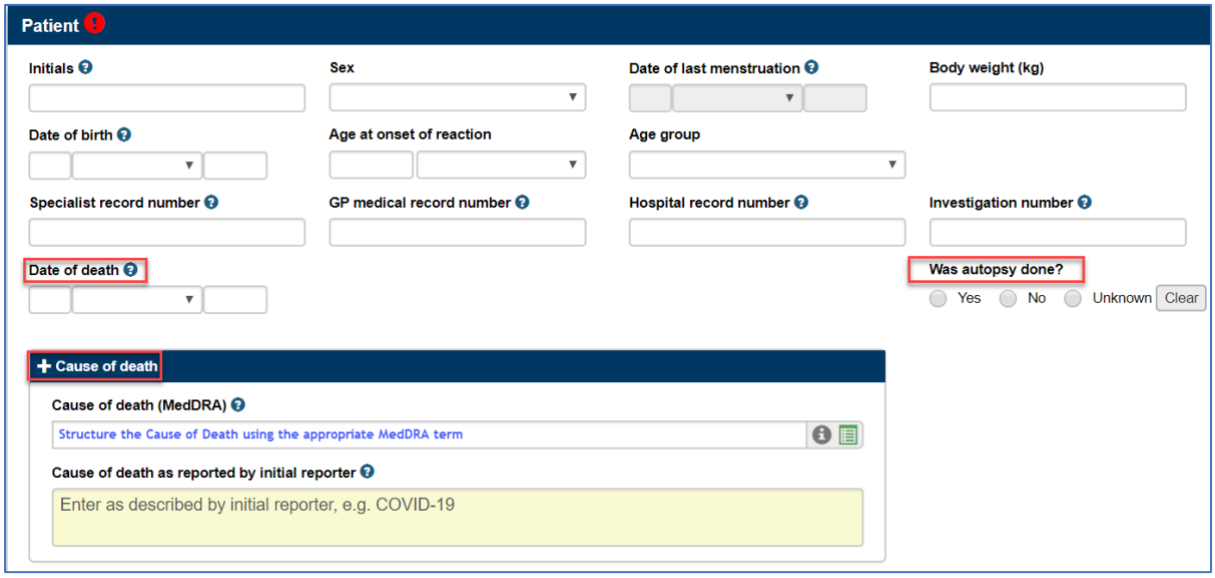
Study name: enter as applicable according to study title (e.g. *An international randomized trial of additional treatments for COVID-19 in hospitalized patients who are all receiving the local standard of care*)

Study sponsor number: enter as applicable (e.g. *0003361*)

Study registration number: enter as applicable

Study registration country: select as applicable

Patient section



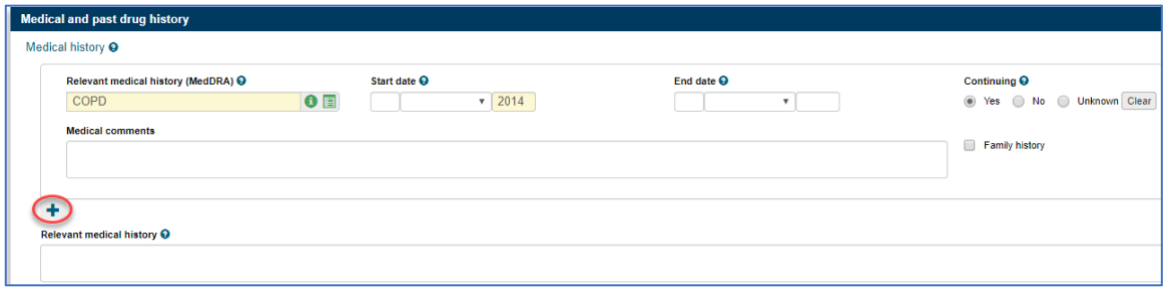
In case of fatal reports, enter the information in the following fields in addition to autopsy information (the fields are available through clicking on 'Additional fields'):

Date of death: reported death date

Cause of death (MedDRA): Structure the Cause of death using the appropriate MedDRA term. Use the +Sign for multiple entries

Cause of death as reported by initial reporter (free text): enter as described by the initial reporter.

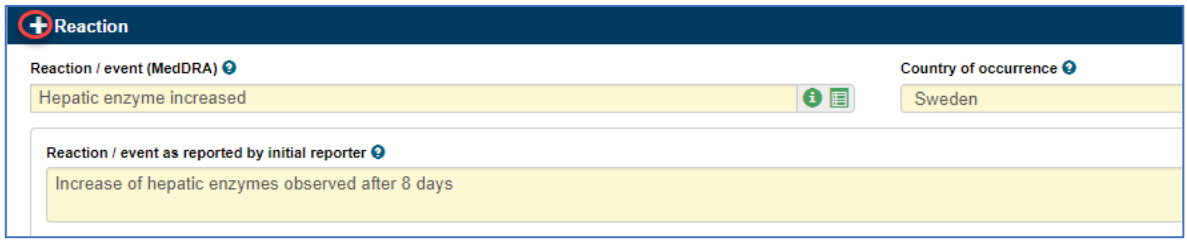
Medical and past drug history section



Relevant medical history (MedDRA): structure the (relevant) pre-existing conditions using MedDRA. Use the +Sign for multiple entries.

Relevant medical history (free text): To be used if not possible to structure medical history using the MedDRA-field.

Adverse reaction section



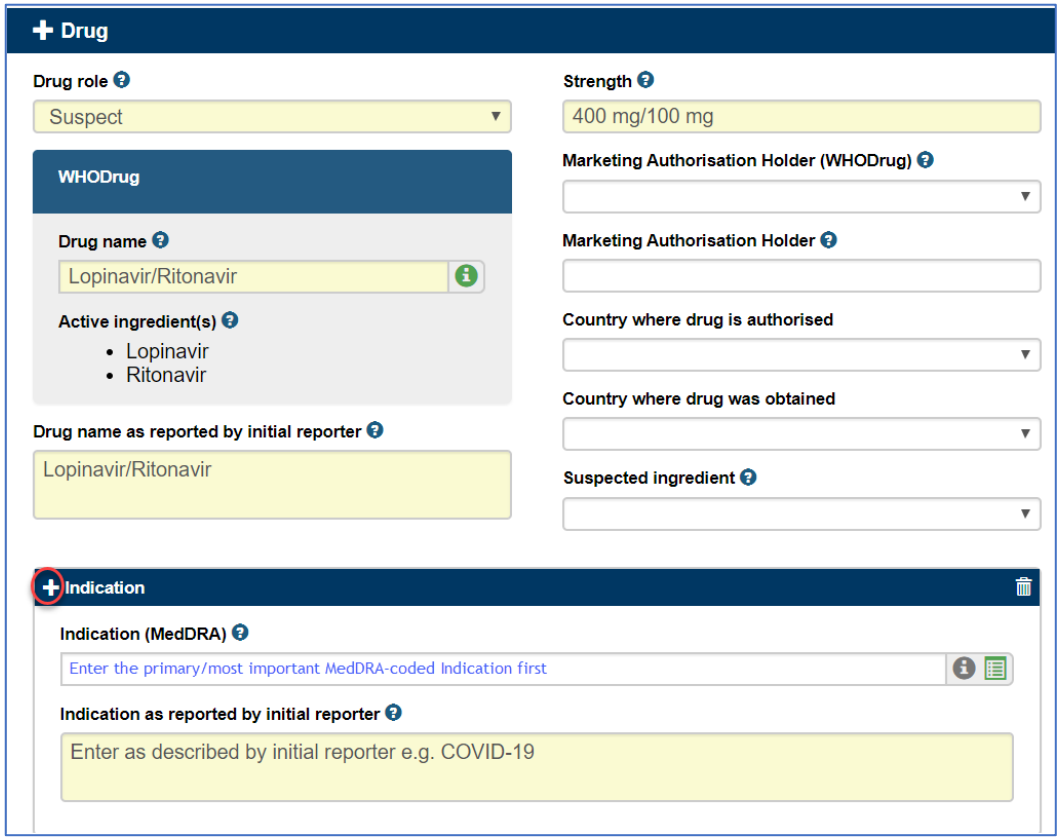
The Adverse reaction section is crucial for pharmacovigilance data and information needs to be captured as precisely as possible.

Reaction/event (MedDRA): Structure the Reaction/event using the appropriate MedDRA term. Use the +Sign to structure multiple reactions e.g. if Lack of therapeutic efficacy or Off-label use is to be entered in addition to an ADR.

Reaction/event as reported by initial reporter: enter the Reaction/event as described by the initial reporter.

Drug section

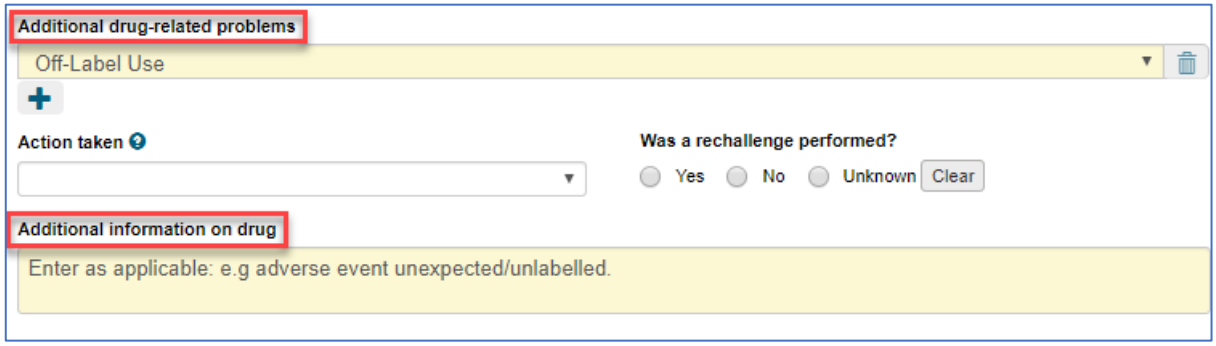
Indication



Indication (MedDRA): Ensure to structure the primary/most important indication first. Use the +Sign to structure multiple indications.

Indication as reported by initial reporter (free text): enter as described by the initial reporter.

Additional drug-related problems and Additional information on drug

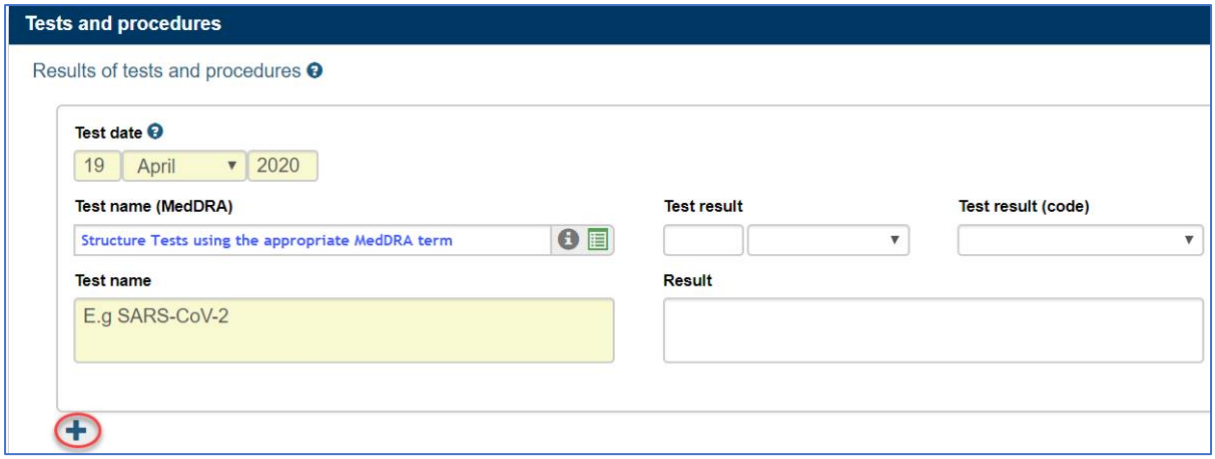


In addition to structuring Off-label use in the adverse event section, the following two fields in the Drug section can also be used:

Additional drug related problems: It is possible to select Off-label use from the dropdown

Additional information on drug: Free-text field that can be used to indicate any additional information on drug such as labelling information with regards to the adverse reaction(s).

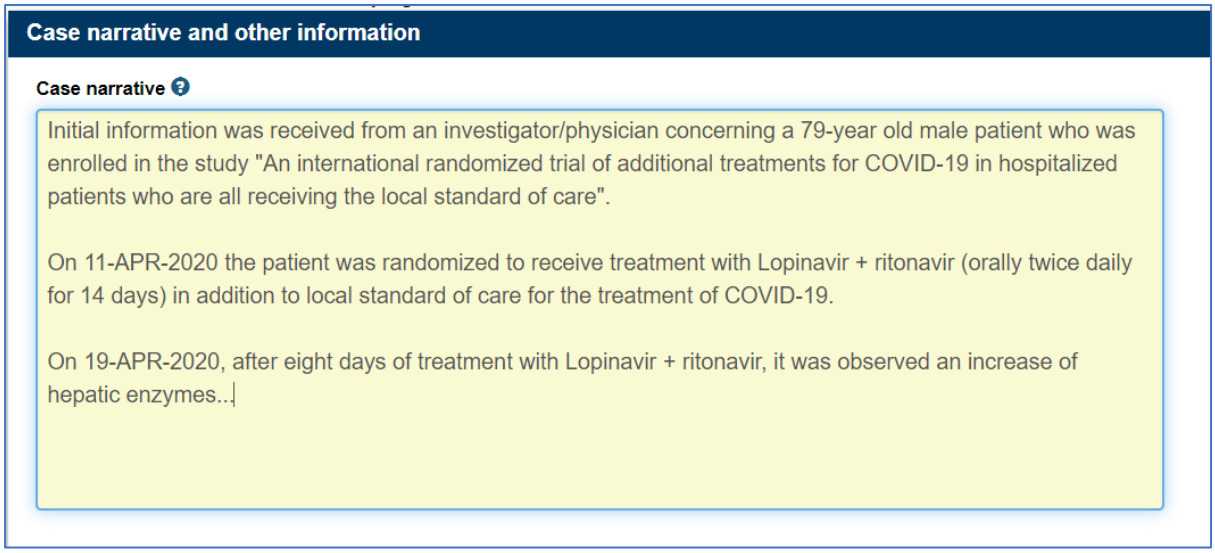
Tests and procedures section



Test name (MedDRA): Structure Tests using the appropriate MedDRA term. Use the +Sign for multiple entries.

Test name (free text): To be used when an appropriate MedDRA term is unavailable.

Case narrative

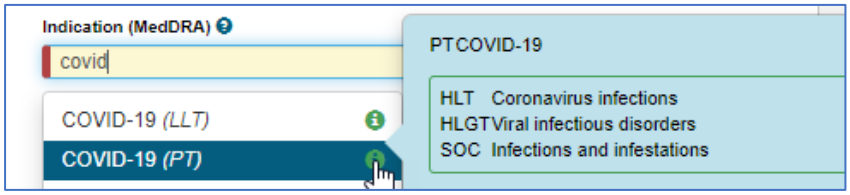


Ensure wise use of the case narrative section to include information in chronological order, using precise terminology to describe the case, including the words or short phrases used by the reporter.

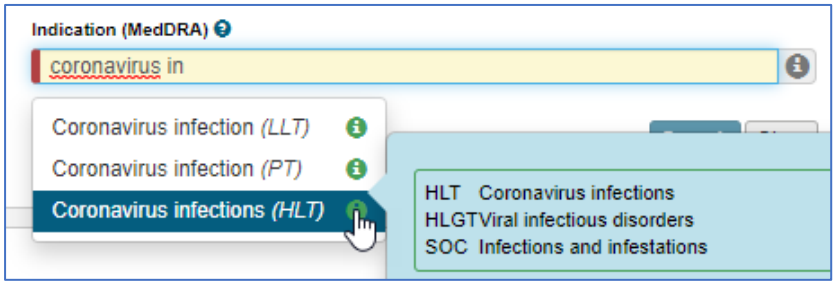
Data retrieval using the Indication filter

Use the search filters in the report list section to retrieve COVID-19 related reports. The most relevant search filter is **Indication filter**, given that the indication is coded in MedDRA as described above.

1a. Indication filter: searching MedDRA PT COVID-19

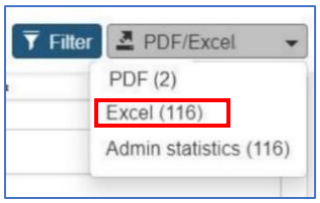


1b. Indication filter: searching MedDRA HLT Coronavirus infections



The case list can be exported to excel for further data analysis and signal detection work.

2. Export the case list to Excel



Sharing COVID-19 related reports with the WHO Programme for International Drug Monitoring

Use the "Send copy" button available within a report, to share the information with the WHO Programme for international Drug Monitoring. Remember that a report can be shared even when having sparse initial data available and can be shared again if further information is obtained.