

# 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

The screenshot shows the 'Report information' section of the VigiFlow interface. A red box highlights the 'Report type' dropdown menu, which is open and shows four options: 'Spontaneous report' (highlighted in blue), 'Report from study', 'Other', and 'Not available to sender (unknown)'. Other visible fields include 'Report title', 'Initial received date' (21 April 2020), and 'Initial report date'. There are also radio buttons for 'Does this case fulfil the local criteria for an expedited report?' with 'Yes' and 'No' options, and a 'Clear' button.

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

The screenshot shows the 'Study information' tab in the VigiFlow interface. The 'Study type' dropdown is set to 'Clinical trials'. The 'Study name' field contains the text: 'Enter as applicable e.g. An international randomized trial of additional treatments for COVID-19 in hospitalized patients who are all receiving the local standard of care.' The 'Study sponsor number' field contains 'Enter as applicable e.g. 0003361'. The 'Study registration number' field contains 'Enter as applicable' and the 'Study registration country' dropdown is set to 'Sweden'. There is also a trash icon and a plus sign at the bottom left.

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

**Patient**

Initials  Sex  Date of last menstruation  Body weight (kg)

Date of birth  Age at onset of reaction  Age group

Specialist record number  GP medical record number  Hospital record number  Investigation number

Date of death  Was autopsy done?  Yes  No  Unknown

**+ Cause of death**

Cause of death (MedDRA)

Structure the Cause of Death using the appropriate MedDRA term

Cause of death as reported by initial reporter

Enter as described by initial reporter, e.g. COVID-19

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

**Medical and past drug history**

Medical history

Relevant medical history (MedDRA)  Start date  End date  Continuing  Yes  No  Unknown

Medical comments

Family history

**+ Relevant medical history**

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 screenshot shows a form titled '+ Reaction'. It contains two main input fields. The first is 'Reaction / event (MedDRA)' with the value 'Hepatic enzyme increased' and a dropdown for 'Country of occurrence' set to 'Sweden'. The second is 'Reaction / event as reported by initial reporter' with the value 'Increase of hepatic enzymes observed after 8 days'.

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

The screenshot shows a form titled '+ Drug' with several fields. 'Drug role' is set to 'Suspect' and 'Strength' is '400 mg/100 mg'. The 'WHODrug' section includes 'Drug name' (Lopinavir/Ritonavir) and 'Active ingredient(s)' (Lopinavir, Ritonavir). Other fields include 'Marketing Authorisation Holder (WHODrug)', 'Marketing Authorisation Holder', 'Country where drug is authorised', 'Country where drug was obtained', and 'Suspected ingredient'. Below the drug section is a sub-section titled '+ Indication' with 'Indication (MedDRA)' (placeholder: 'Enter the primary/most important MedDRA-coded Indication first') and 'Indication as reported by initial reporter' (placeholder: 'Enter as described by initial reporter e.g. COVID-19').

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

The screenshot shows two sections of a form. The first section, titled 'Additional drug-related problems', has a dropdown menu currently set to 'Off-Label Use'. Below this is a plus sign icon and a label 'Action taken' with a question mark icon and a dropdown menu. To the right is a label 'Was a rechallenge performed?' with three radio buttons labeled 'Yes', 'No', and 'Unknown', and a 'Clear' button. The second section, titled 'Additional information on drug', contains a text input field with the placeholder text 'Enter as applicable: e.g adverse event unexpected/unlabelled.'

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

The screenshot shows the 'Tests and procedures' section of a form. It has a dark blue header with the title 'Tests and procedures'. Below the header is a label 'Results of tests and procedures' with a question mark icon. The main content area contains a 'Test date' field with a date picker set to '19 April 2020'. Below this is a 'Test name (MedDRA)' field with a dropdown menu showing 'Structure Tests using the appropriate MedDRA term' and a plus sign icon. To the right of this field are two dropdown menus labeled 'Test result' and 'Test result (code)'. Below the 'Test name (MedDRA)' field is a 'Test name' field with a text input containing 'E.g SARS-CoV-2'. Below the 'Test name' field is a 'Result' field with a text input. At the bottom left of the form is a plus sign icon in a red circle.

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

### Case narrative and other information

**Case narrative ?**

Initial information was received from an investigator/physician concerning a 79-year old male patient who was enrolled in the study "An international randomized trial of additional treatments for COVID-19 in hospitalized patients who are all receiving the local standard of care".

On 11-APR-2020 the patient was randomized to receive treatment with Lopinavir + ritonavir (orally twice daily for 14 days) in addition to local standard of care for the treatment of COVID-19.

On 19-APR-2020, after eight days of treatment with Lopinavir + ritonavir, it was observed an increase of hepatic enzymes...]

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

Indication (MedDRA) ?

covid

COVID-19 (LLT) ⓘ

COVID-19 (PT) ⓘ

PTCOVID-19

- HLT Coronavirus infections
- HLGT Viral infectious disorders
- SOC Infections and infestations

1b. Indication filter: searching MedDRA HLT Coronavirus infections

Indication (MedDRA) ?

coronavirus in ⓘ

Coronavirus infection (LLT) ⓘ

Coronavirus infection (PT) ⓘ

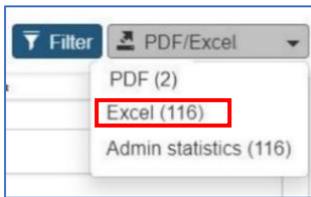
Coronavirus infections (HLT) ⓘ

PTCOVID-19

- HLT Coronavirus infections
- HLGT Viral infectious disorders
- SOC Infections and infestations

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.

