

Using VigiFlow to collect and monitor Adverse Events Following Immunization for Covid-19 vaccinations

The WHO Covid-19 vaccines safety [surveillance manual](#) states that VigiFlow is the recommended tool for Covid-19 vaccine-related AEFI reporting, especially in settings where no other electronic tool is available. VigiFlow enables collaborative efforts between the national immunization programme (NIP) and the national PV centre (NC) in collecting and monitoring AEFIs following Covid-19 vaccinations, by supporting the respective needs and processes.

This document considers some aspects on how VigiFlow efficiently supports the collection and monitoring of adverse events following immunization (AEFI) connected to Covid-19 vaccinations. *If you want to know more, please reach out to us: vigibase@who-umc.org.*

Data entry: ICSR form or AEFI form?

In VigiFlow there are two different reporting forms available to support manual data entry of adverse events following immunization: the *AEFI form* and the *ICSR form*.



The recent inclusion of the AEFI form is based on the WHO reporting form for AEFIs. As outlined in the WHO manual, the form enables comprehensive and complete collection of all key descriptive epidemiological data (*time, place and person*) that are critical for identifying clusters and for signal detection. The AEFI form also includes possibilities to enter information relevant for the quality of the surveillance system in terms of the completeness and timeliness of the reporting. The VigiFlow AEFI form aims to support settings where these processes are implemented. Other organisations/settings may use either the ICSR form or AEFI form for initial data entry, whichever suits the process and information scope in that specific setting.

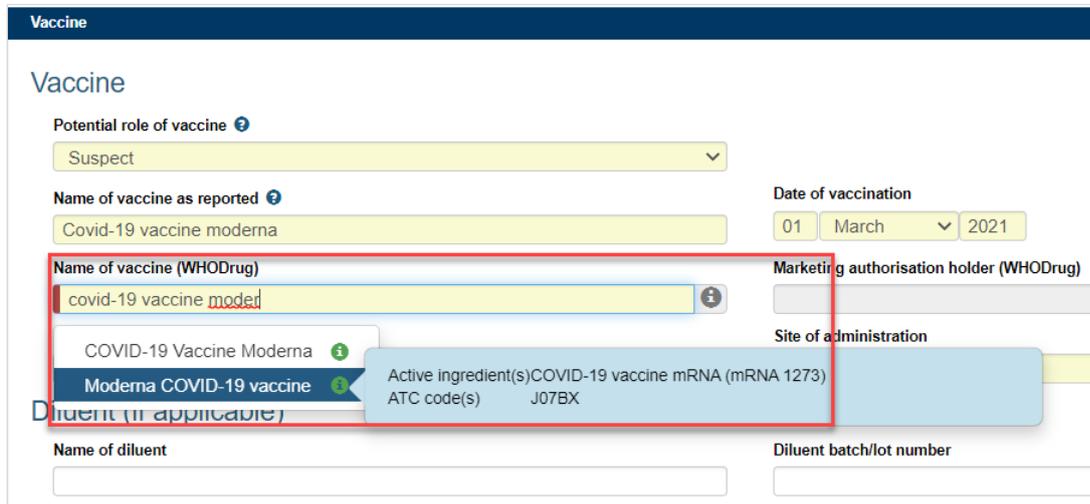
This means that the organization using VigiFlow needs to decide which form and process that best supports their setting. As VigiFlow allows a report to be viewed in both ICSR and AEFI format the forms can be used solely or in combination, allowing flexible approaches for data entry and data processing.

Some specific guidance on how to enter data in the AEFI form is available in short video instructions on the UMC website: [Global pharmacovigilance → VigiFlow → Training Materials → English](#)

Finding the Covid-19 vaccines and corresponding Marketing Authorization Holders (MAHs) in WHODrug

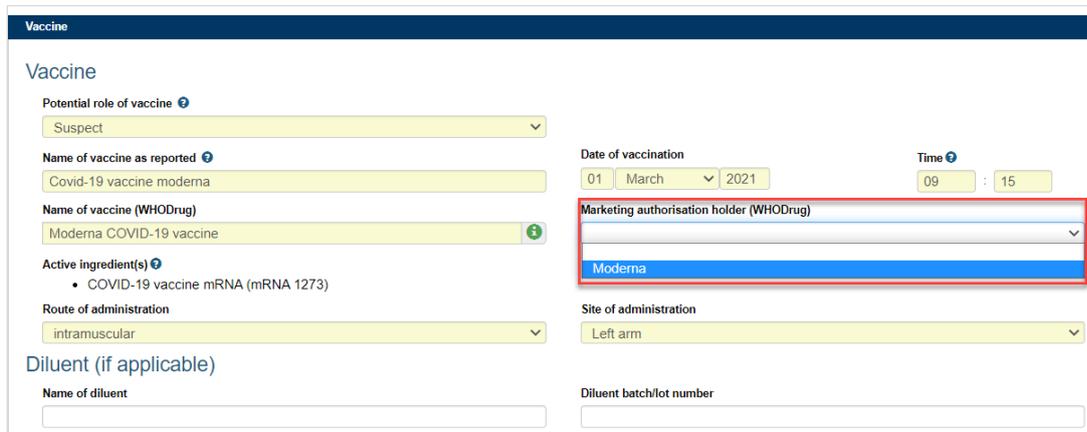
As outlined in the WHO Covid-19 vaccines safety surveillance manual it is important to capture the Covid-19 vaccine brand name, manufacturer/marketing authorization holder, as well as the batch number as multiple Covid-19 vaccines might be in use simultaneously within a country. The availability of the WHODrug dictionary in VigiFlow supports a consistent capturing of the name and corresponding manufacturer/marketing authorization holder information. Using WHODrug will facilitate the analysis/signal detection steps by ensuring consistent data capturing, hence also data retrieval of the vaccine. The below pictures show examples on how the Covid-19 vaccine information can be captured in the AEFI form in VigiFlow:

Finding the vaccine in the WHODrug dictionary field “Name of vaccine (WHODrug)”:



The screenshot shows the 'Vaccine' form in VigiFlow. The 'Name of vaccine (WHODrug)' field is highlighted with a red box, and a dropdown menu is open showing 'Moderna COVID-19 vaccine' selected. A tooltip for 'Moderna COVID-19 vaccine' is visible, showing 'Active ingredient(s) COVID-19 vaccine mRNA (mRNA 1273)' and 'ATC code(s) J07BX'. Other fields include 'Potential role of vaccine' (Suspect), 'Name of vaccine as reported' (Covid-19 vaccine moderna), 'Date of vaccination' (01 March 2021), 'Marketing authorisation holder (WHODrug)', 'Site of administration', 'Name of diluent', and 'Diluent batch/lot number'.

Finding the corresponding MAH in the filed “Marketing authorization holder (WHODrug)”:



The screenshot shows the 'Vaccine' form in VigiFlow. The 'Marketing authorisation holder (WHODrug)' field is highlighted with a red box, and a dropdown menu is open showing 'Moderna' selected. Other fields include 'Potential role of vaccine' (Suspect), 'Name of vaccine as reported' (Covid-19 vaccine moderna), 'Name of vaccine (WHODrug)' (Moderna COVID-19 vaccine), 'Active ingredient(s)' (COVID-19 vaccine mRNA (mRNA 1273)), 'Route of administration' (intramuscular), 'Date of vaccination' (01 March 2021, 09:15), 'Site of administration' (Left arm), 'Name of diluent', and 'Diluent batch/lot number'.

When not possible to find the MAH in WHODrug, use the free text field to capture the information:



Vaccine

Potential role of vaccine
Suspect

Name of vaccine as reported
Covid-19 vaccine Sinopharm

Name of vaccine (WHODrug)
BBIBP-CorV

Active ingredient(s)
• COVID-19 vaccine inact (Vero) HB02

Date of vaccination
Time

Dose number
Batch/lot number

Marketing authorisation holder (WHODrug)

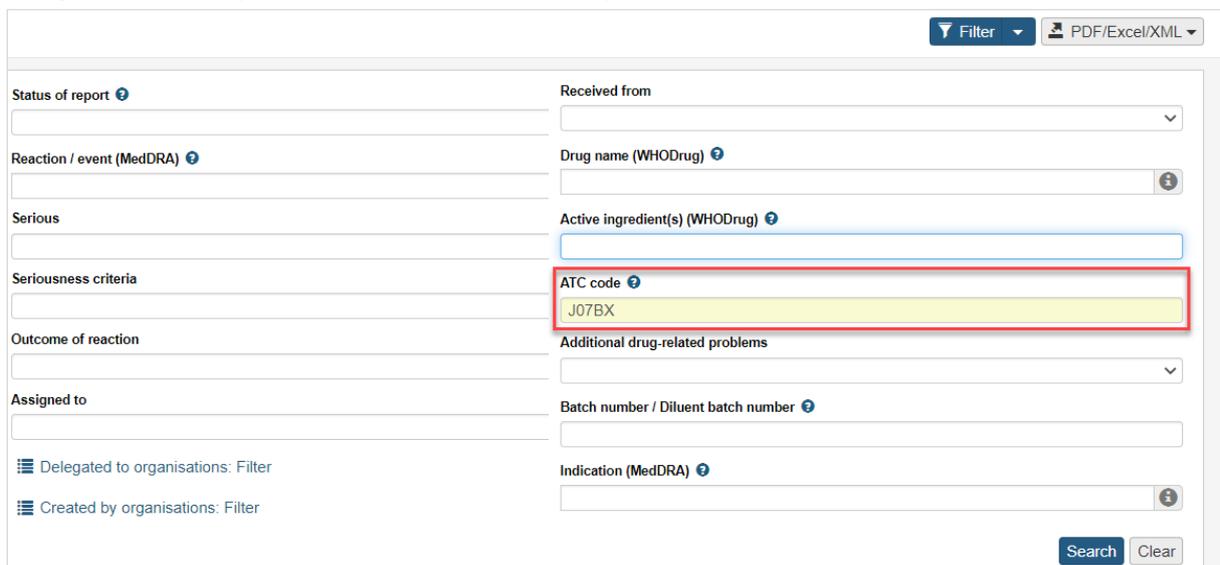
Marketing authorisation holder/Manufacturer
Sinopharm

Please note that WHODrug is continuously expanded with additional information meaning that a Covid-19 vaccine that was missing yesterday might be available the next day. But most important, if you notice that a vaccine, medicinal product or the corresponding manufacturer/marketing authorization holder is missing in WHODrug, we encourage you to request it to be added. Send an e-mail to vigibase@who-umc.org including information about vaccine/drug name, ingredients, marketing authorization holder and a link to a reference e.g. the national drug library (form and strength can be included as applicable).

Retrieving/Searching for Covid-19 vaccine reports

The report list filters are used to retrieve the Covid-19 vaccine reports that you want to show in the report list. If you want to do a broad search retrieving all the Covid-19 vaccine reports you have in VigiFlow, the “ATC code” filter best supports this search. The Covid-19 vaccines are assigned with the ATC-code J07BX (note that this ATC search might retrieve other viral vaccine reports in addition to Covid-19 vaccine reports).

Using the ATC code filter to retrieve all Covid-19 reports:



Filter PDF/Excel/XML

Status of report
Received from

Reaction / event (MedDRA)
Drug name (WHODrug)

Serious
Active ingredient(s) (WHODrug)

Seriousness criteria
ATC code
J07BX

Outcome of reaction
Additional drug-related problems

Assigned to
Batch number / Diluent batch number

Delegated to organisations: Filter
Indication (MedDRA)

Created by organisations: Filter

Search Clear

The filters “*Drug name (WHODrug)*” and “*Active ingredient(s) (WHODrug)*” are to be used when you want to retrieve reports by each of the Covid-19 vaccines one at the time, respectively. The filters will only retrieve exact matches dependent on how the Covid-19 vaccine was coded in the WHODrug data entry field. This means that a search for “Covid-19 Vaccine Moderna” in the “*Drug name (WHODrug)*” filter will show only reports where the vaccine is coded to “Covid-19 Vaccine Moderna” but not reports where the vaccine is coded to “Moderna Covid-19 vaccine”.

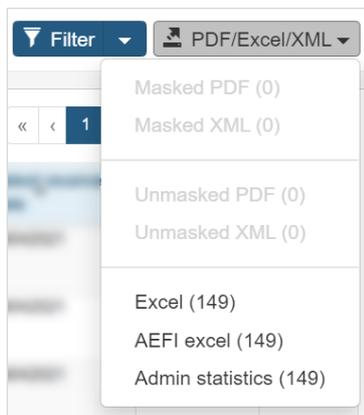
Data export: Excel or AEFI excel?

In VigiFlow there are two different excels presenting the data in a line listing format; *Excel* and *AEFI Excel*. Both the excels retrieve reports based on the filters applied to the report list, independently on which data entry form was used to enter the data in VigiFlow. For example, this means that data entered through the AEFI form can be retrieved to both the AEFI Excel and the Excel, as applicable to the user needs.

Referring to the WHO Covid-19 vaccines safety surveillance manual, the AEFI excel in VigiFlow provides key descriptive epidemiological data critical for identifying clusters and for signal detection. In addition, it includes the relevant data to monitor the quality of the AEFI surveillance system in terms of completeness and timeliness of the reporting.

The VigiFlow Excel includes complementary data typically relevant in signal detection processes such as the MedDRA hierarchy.

Excel and AEFI Excel:



Sharing Covid-19 vaccine reports with the WHO global database

The WHO Covid-19 vaccines safety surveillance manual states that the national pharmacovigilance centres are expected to share AEFI data with the WHO Global database. In VigiFlow this is directly supported by using the “Send copy” button available within a report. Note that this action can only be performed by the National PV Centre level in VigiFlow.

Sharing Covid-19 vaccine data with the WHO global database within a report:

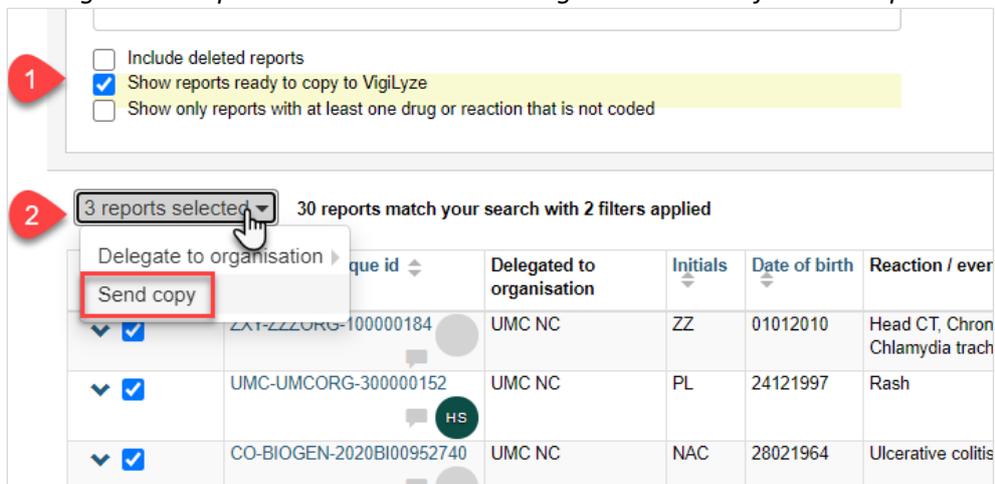


Remember that a report can be shared even when having sparse initial data available and can be shared again if further information is obtained.

It is also possible to share several reports at once directly from the main report list.

The filter ‘Show reports ready to copy to VigiLyze’ can be used to easily find reports that are ready to be shared with VigiLyze. Select the reports you wish to send (checking the tick boxes) and choose “Send copy” in the menu just above the Report List.

Sharing several reports at once with the WHO global database from the report list:



A screenshot of the VigiFlow report list interface. It shows a filter section with three options: 'Include deleted reports' (unchecked), 'Show reports ready to copy to VigiLyze' (checked), and 'Show only reports with at least one drug or reaction that is not coded' (unchecked). Below the filters, a dropdown menu shows '3 reports selected' and '30 reports match your search with 2 filters applied'. A table of reports is displayed with columns for 'Unique id', 'Delegated to organisation', 'Initials', 'Date of birth', and 'Reaction / event'. The 'Send copy' button is highlighted with a red box in the dropdown menu.

Unique id	Delegated to organisation	Initials	Date of birth	Reaction / event
UMC-UMCORG-100000184	UMC NC	ZZ	01012010	Head CT, Chron Chlamydia trach
UMC-UMCORG-300000152	UMC NC	PL	24121997	Rash
CO-BIOGEN-2020BI00952740	UMC NC	NAC	28021964	Ulcerative colitis