

# Uppsala Monitoring Centre

## Making Medicines Safer

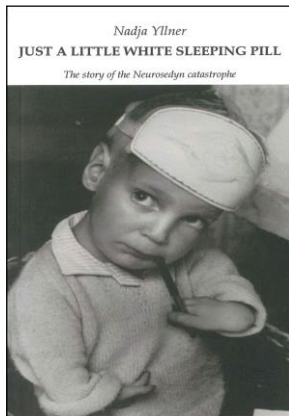


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Research & Education Department



– Building a global safety culture

# WHO Programme for International Drug Monitoring



1961 Thalidomide



World Health  
Organization

1968 WHO creates  
the Programme for  
International Drug  
Monitoring (WHO PIDM)

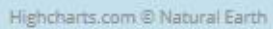


Uppsala  
Monitoring  
Centre

1978 WHO and  
Swedish Government  
creates the WHO  
Collaborating Centre

# Aim of the WHO PIDM

To ensure that early signs of previously unknown medicine-related safety problems are **identified** and information about them **shared** and **acted upon**.



Full members: 140  
Associate members: 30  
Total: 170



# WHO PIDM Annual Meeting

## WHO Programme Annual Meeting

*Each year the Annual Meeting of Representatives of National Pharmacovigilance Centres takes place in a member country of the WHO Programme for International Drug Monitoring.*

### 43rd Annual Meeting

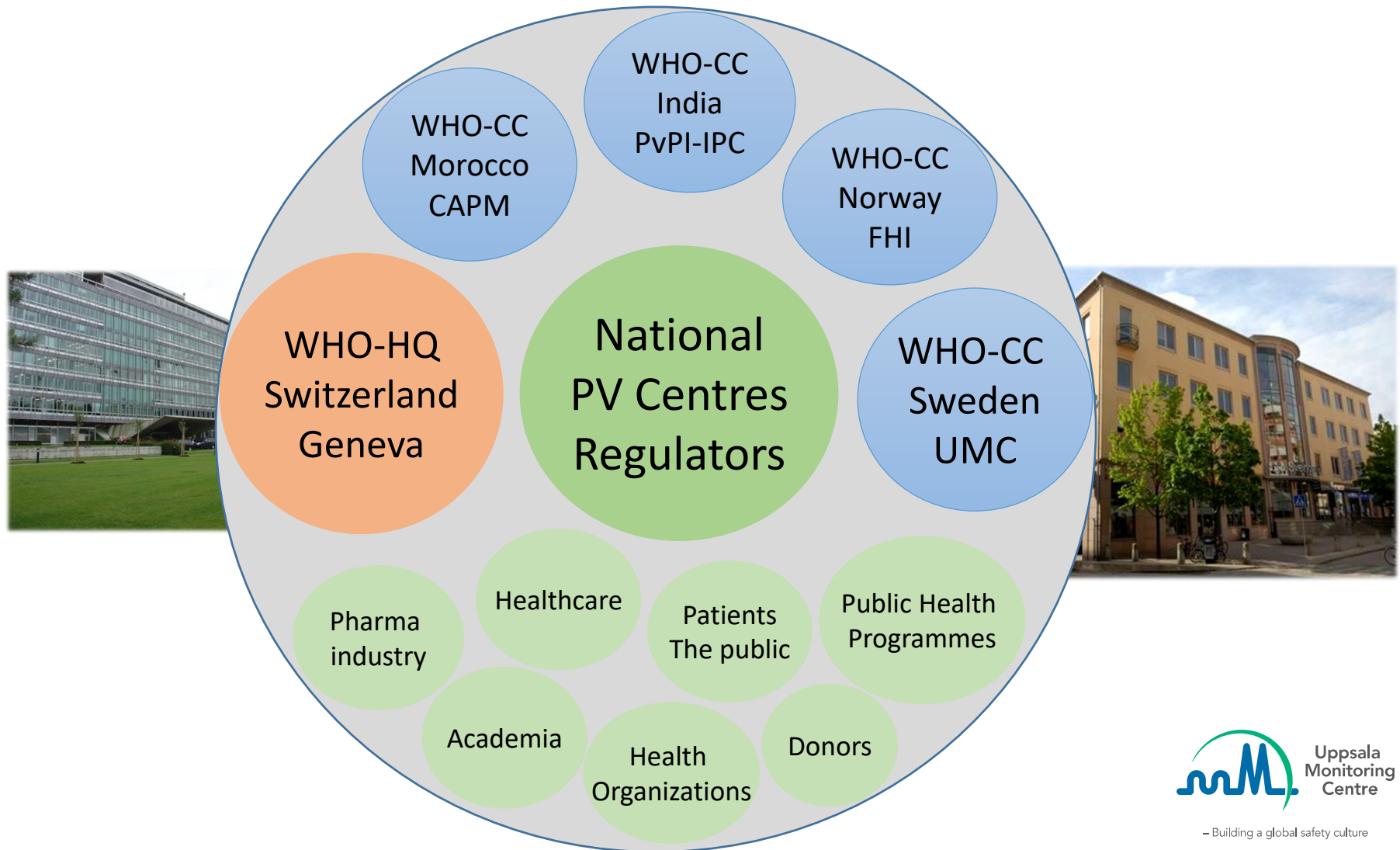
**Date:** the 2020 meeting has been postponed

**Location:** New Delhi, India

WHO Programme Annual Meeting



# PV Stakeholder Overview

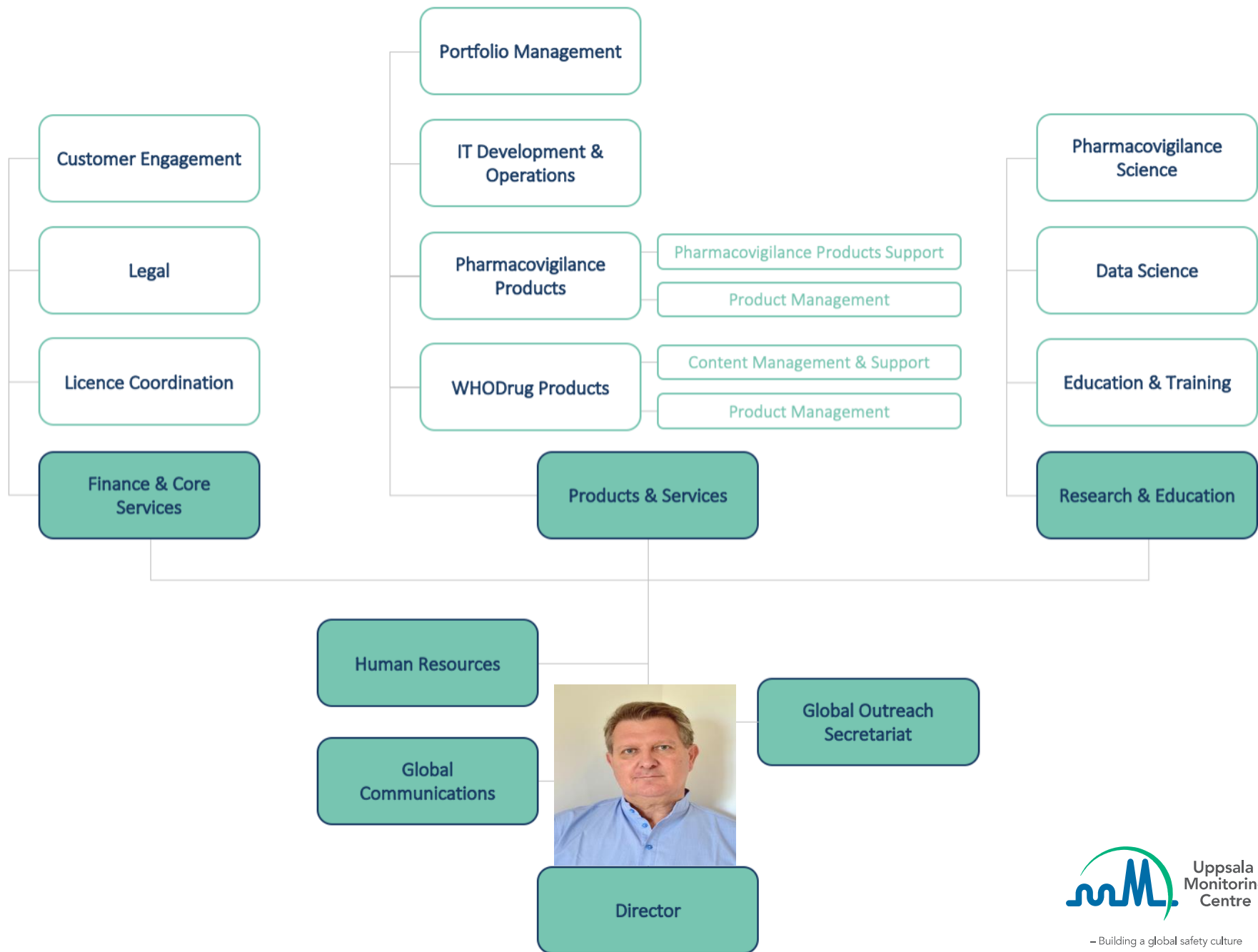


# Uppsala Monitoring Centre (UMC)

*WHO Collaborating Centre for International Drug Monitoring*

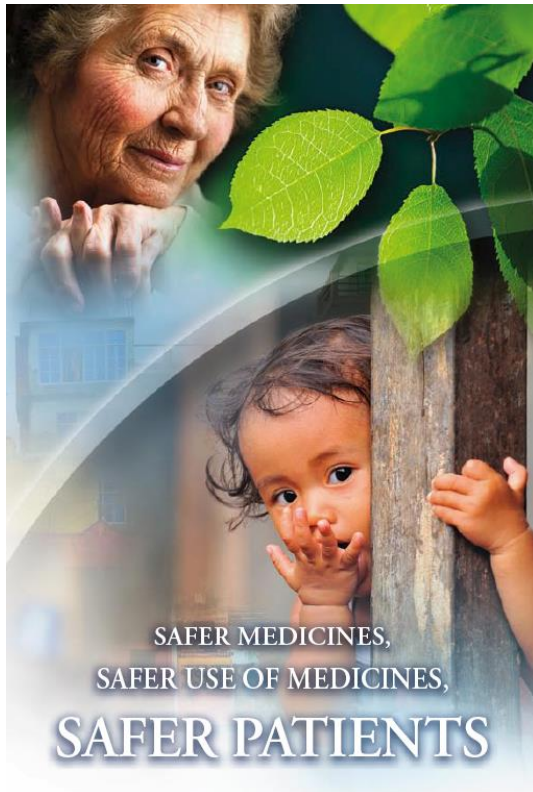
- Non-profit foundation since 1978
- Provides scientific leadership and operational support to the WHO PIDM
- Manages Vigibase
- Maintains WHODrug Global
- Independent and self-funded
- International board







# UMC Vision and Mission

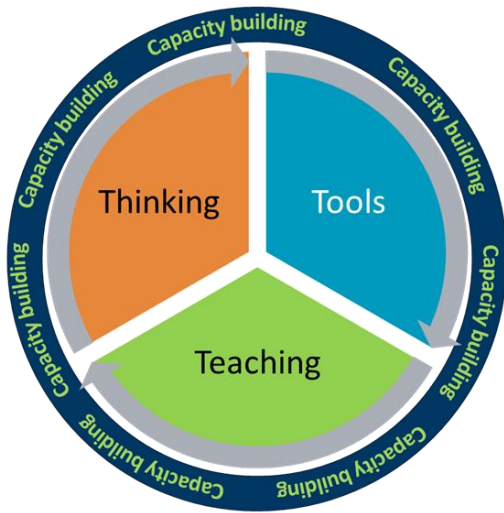


**A world where all patients and health professionals make wise therapeutic decisions in their use of medicines**

**Support and promote patient safety through effective and global pharmacovigilance practice**

# Work Areas

- Provision of technology and support *tools*
- *Teaching*, training and advocacy
- Scientific development (*thinking*)



# Provision of Technology and Support Tools

## PV tools

- Vigiflow
- Vigilyze
- Vigaccess

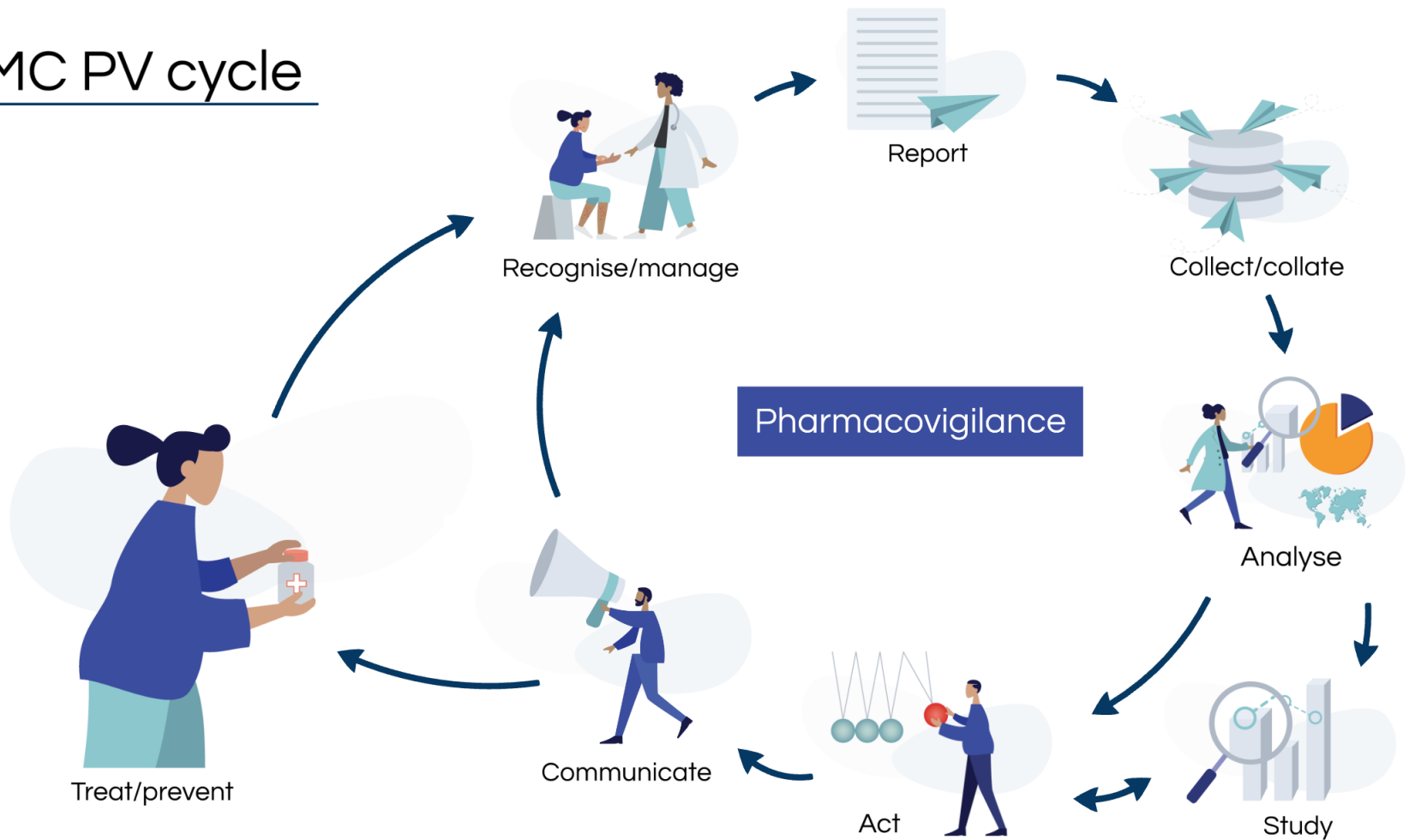
## Clinical information

- Vigibase

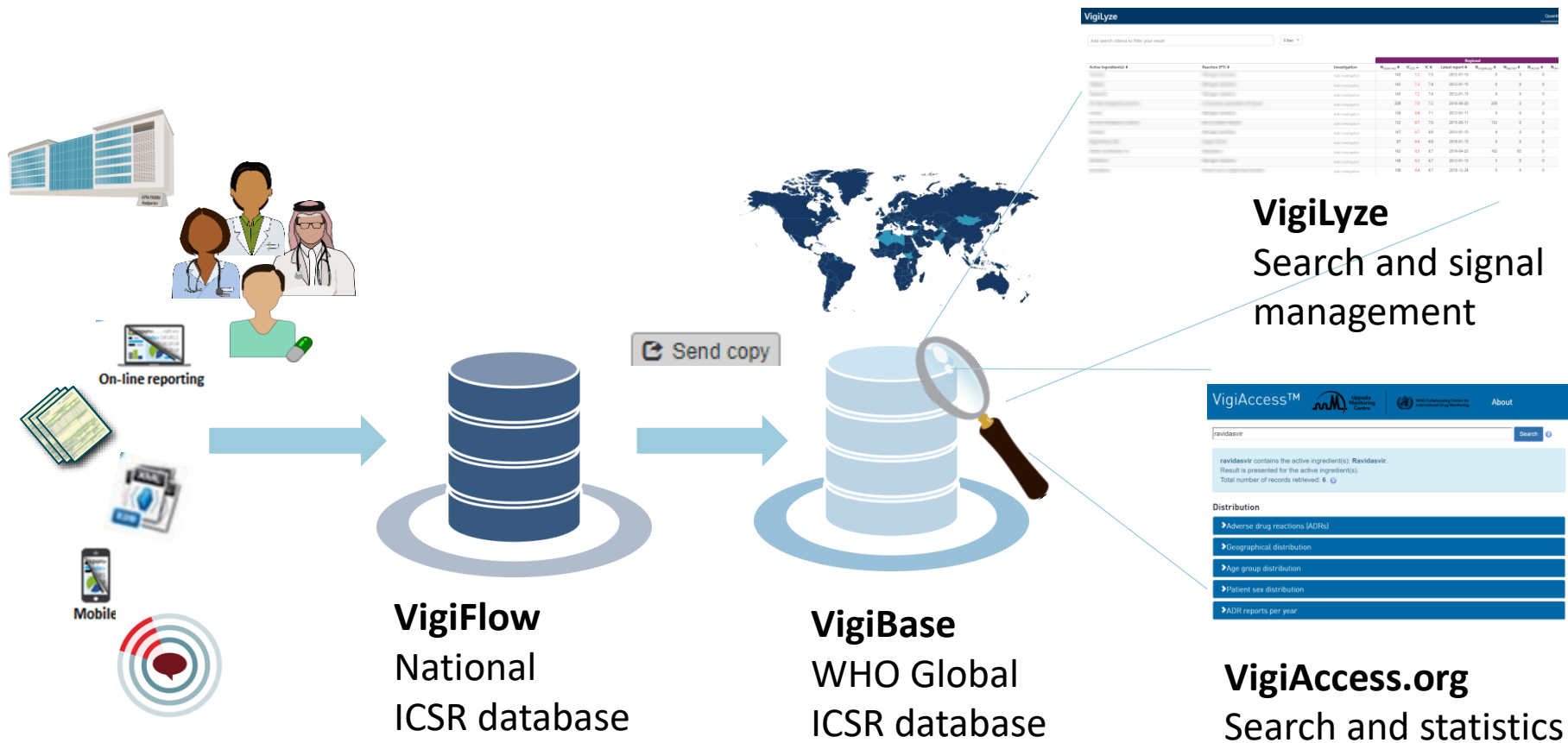
## Dictionaries and terminologies

- WHODrug Global
- (MedDRA)

# UMC PV cycle



# The Flow of ICSRs





# VigiFlow – ICSR Data Management

- Collect, process, analyse and share ICSRs
- Web based and ICH E2B compliant
- WHODrug/MedDRA
- ADRs and AEFIs\*
- For national (and regional) PV centres

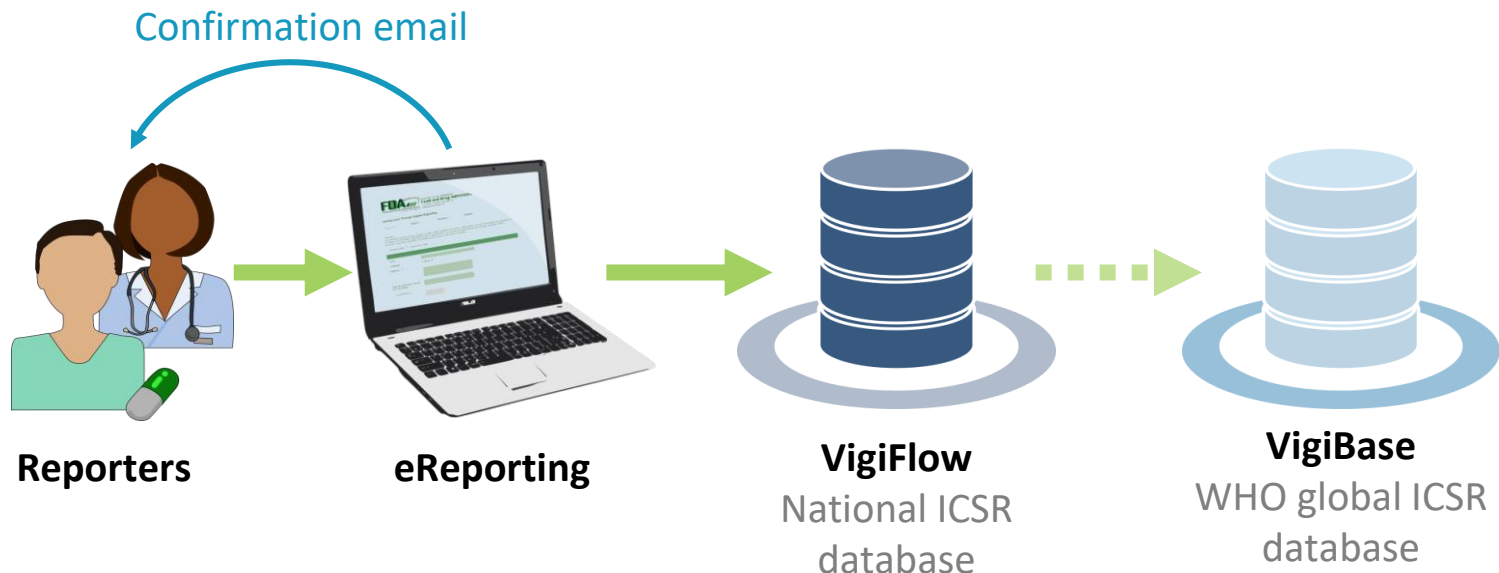


\*AEFI = Adverse Event Following Immunization

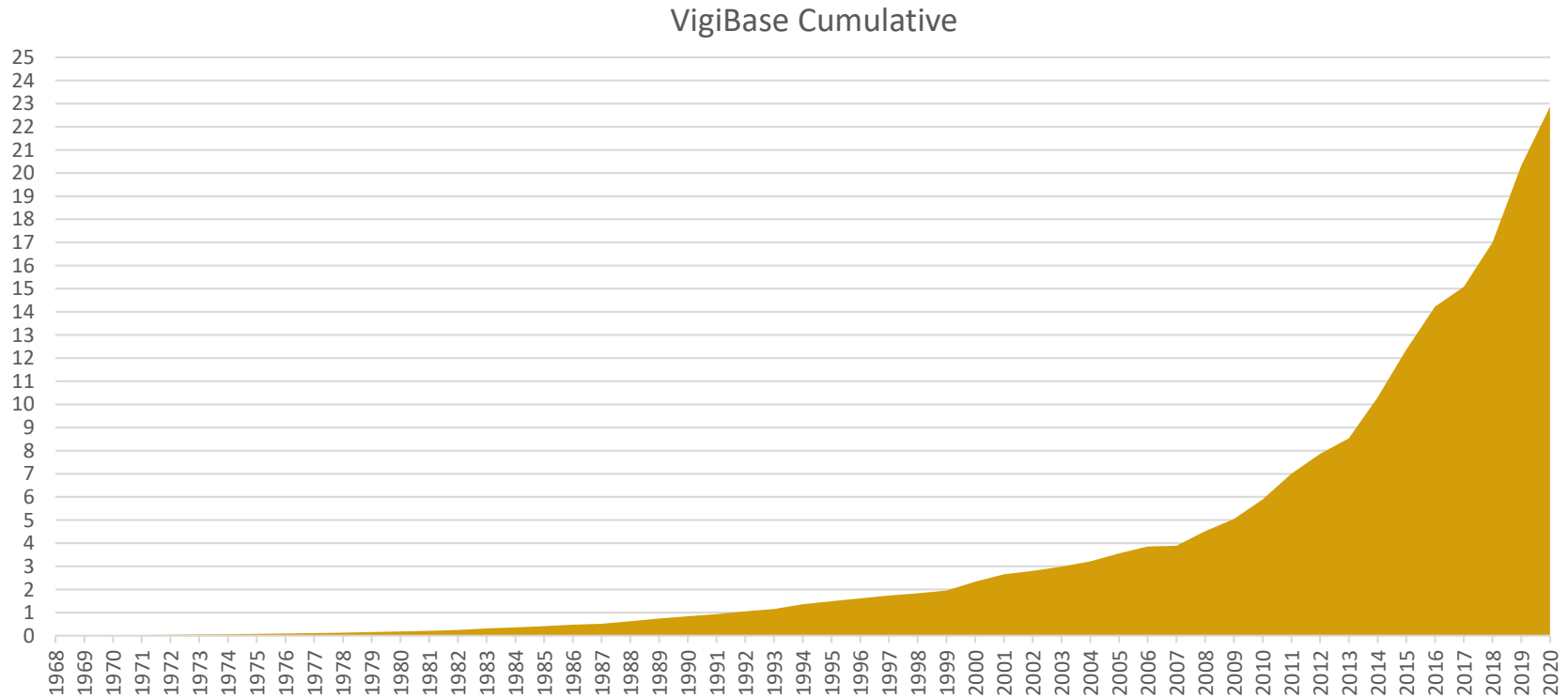
# eReporting – An add-on module to Vigiflow

To facilitate electronic reporting from patients, healthcare professionals and pharma industry

- *No delay in receiving the reports*
- *Off-loading the national PV centres*



# VigiBase – The WHO Global ICSR Database

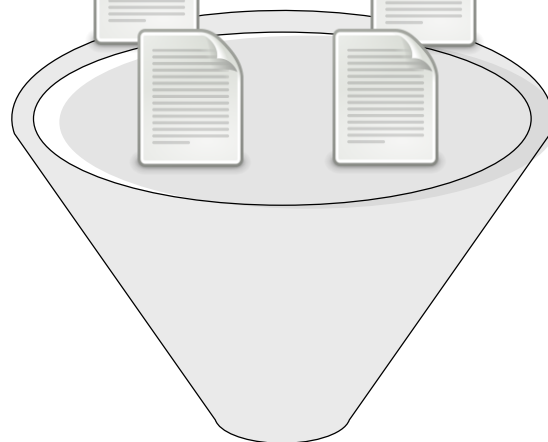


**> 20 million Individual Case Safety Reports (ICSRs)**

# WHO Drug



# MedDRA



# WHODrug Global

- Drug reference dictionary + analytical tools
- Pharma companies / CROs
- Medicinal product info
- Biannual updates
- English and Chinese







# VigiLyze – Signal Management

- Web based tool to access VigiBase
- Graphical overview of data
- Search and analysis functions
- For national (and regional) PV centres




# VigiAccess – For the Public

VigiAccess™Uppsala Monitoring Centre

WHO Collaborating Centre for International Drug Monitoring

About

Search 

Paracetamol contains the active ingredient(s): **Paracetamol**.  
Result is presented for the active ingredient(s).  
Total number of records retrieved: **72783**.

### Distribution

▶ Adverse drug reactions (ADRs)

▶ Geographical distribution

▶ Age group distribution

▶ Patient sex distribution

▶ ADR reports per year

[www.vigiaccess.org](http://www.vigiaccess.org)

# Training Offerings



## 5<sup>TH</sup> ASIA PACIFIC PHARMACOVIGILANCE TRAINING COURSE

March 4-15, 2019  
New Delhi, India

6th ISoP-UMC Training  
Guayaquil, Ecuador  
24-26 September 2018

Pharmacovigilance concepts and  
tools in Latin America.

[BOOK YOUR PLACE NOW](#)



## New Online Course

Sign Up today!



General pharmacovigilance [PLAY ALL](#)

This playlist serves as a store of learning resources on various aspects of pharmacovigilance



The Future of  
Pharmacovigilance



The Need for  
Pharmacovigilance



WHO Programme for  
International Drug



Public Health Programmes  
from a Pharmacovigilance

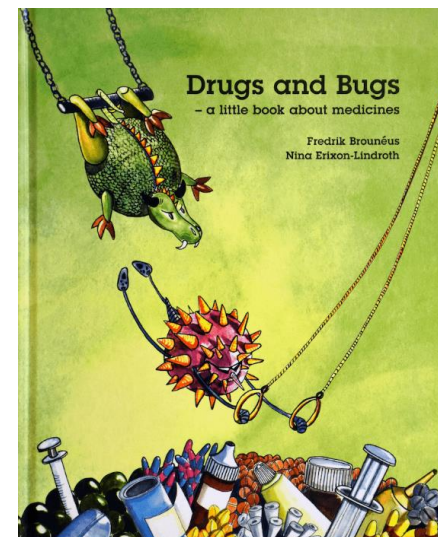
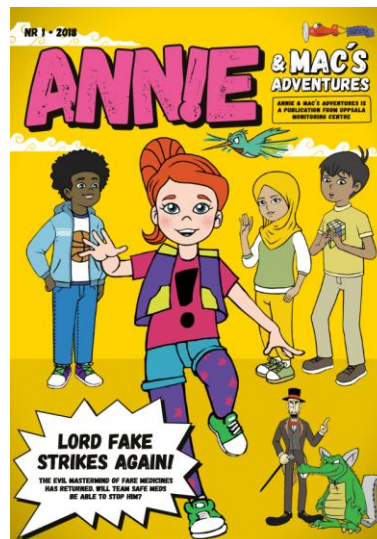


Funding Pharmacovigilance  
Uppsala Monitoring Centre



– Building a global safety culture

# Advocacy - Raising PV Awareness



<https://youtu.be/89lwQmddQrQ>




# Uppsala Reports






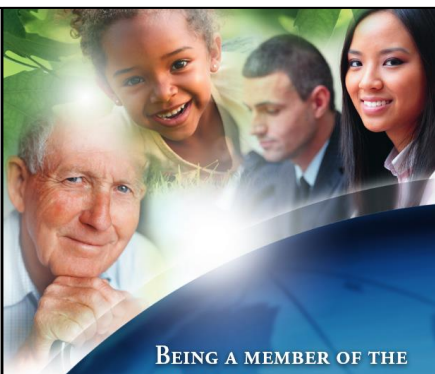
# UMC Publications



World Health Organization

## SAFETY MONITORING of MEDICINAL PRODUCTS


Guidelines for setting up and running a Pharmacovigilance Centre

## BEING A MEMBER OF THE WHO PROGRAMME FOR INTERNATIONAL DRUG MONITORING



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WHO Collaborating Centre for International Drug Monitoring

Inspire. Engage. Transform.

## Sharing pharmacovigilance data in the WHO Programme for International Drug Monitoring

### Reporting fact sheet

The appointed National Centre (NC) for Pharmacovigilance (PV) in each member country is responsible for sharing their Individual Case Safety Reports (ICSRs) with other members of the WHO Programme for International Drug Monitoring by sending the ICSR to Uppsala Monitoring Centre (UMC). For inclusion in Vigibase, the WHO global ICSR database.

**Transmission options**  
NCs can send ICSR to UMC either as e-mail attachments (preferably as encrypted files), via Extranet from where UMC can then download data (the countries in EEA), or on a CD by regular mail. UMC also provides an API (Application Programming Interface) for countries that wish to fully automate the transmission process using secure web-based communication.

**Frequency of transmissions**  
Member countries are expected to share their PV data on a regular basis, preferably more often than once a month, and at the very least every quarter, to keep Vigibase as up-to-date as possible.

**Avoiding the shortest possible lag time from the event to availability of the ICSR in Vigibase is important in order to facilitate early discovery of any potential safety signals in the data – the core mission of the WHO Programme.**

**Case report exchange standards**  
Only ICSR data electronically are accepted. Case reports should be submitted according to the international standard for PV information exchange, ICH E2b. This standard and format is used both by NCs and companies, and allows for


**Vigibase**  
For member countries lacking an ICSR compatible database for ICSR management, UMC has developed Vigibase, a web-based ICSR management system. Copies of the domestic data can easily be shared with the WHO Programme by an automated service to Vigibase.

**What information to share**  
All adverse events occurring in a post-marketing situation and qualifying for your national ICSR database should be shared with the other members of the WHO Programme, both serious and non-serious cases. Vigibase is mainly a database for spontaneous ICSR on registered medicinal products. However, UMC also accepts cases from clinical trials and literature, the type of report should be specified in the ICSR.

ICSRs on medication errors, counterfeit substandard medicines and therapeutic failure should also be submitted. ICSR on ordinary therapeutic medicines, traditional medicines (herbals), as well as biological medicines, including vaccines, should be shared. Medicines in combination with medical devices (the example could event) should also be sent.

ICSRs on veterinary medicines, cosmetic hygiene products or medical devices (not containing any active substances) are not within the scope of the WHO Programme and should not be shared in Vigibase.

**Case report content – quality versus quantity**  
The minimum information required for an ICSR to be valid is a case identifier, response and patient information, and



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## The form of the form

### Examples and good practice in designing an ADR reporting form

A national Adverse Drug Reaction (ADR) reporting form is used for collecting information about a suspected adverse event for analysis at a national pharmacovigilance centre. This document will help you design a user-friendly form and ease the process of submitting reports.

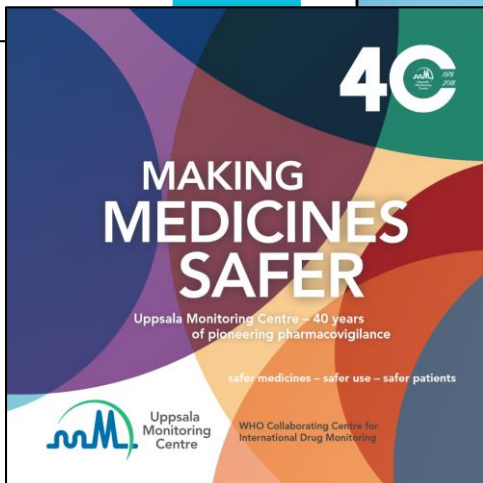
ADR forms are still the main way for sharing information between people who experience an adverse event and decision makers in the national healthcare system. Correct and timely information is necessary to make the risk-benefit analysis of medicines that can prevent future problems. This document will focus on ADR forms, both printed and online, for reporting Individual Case Safety Reports (ICSRs).

A well designed form will encourage and support the reporter in providing good quality ICSRs.

Helping the reporter to understand the ADR form and making the workflow as easy as possible is an important part of successful pharmacovigilance. Another important aspect of making ADR forms is to decide what information you need to collect, to know more about that, please read the UMC's document "ICSRs and Vigibase – the vital importance of quality" (available on the UMC homepage via this link).

## Know your reporter

The first question to ask when designing an ADR form is 'who will fill it in?' Will it be a healthcare professional or a patient? Will the form be filled in under stress before seeing the next patient or done carefully at home? The answer to this question will influence all other decisions you make about the design of the form. Figure 1 shows the patient online reporting form in Australia where the patient is asked for their story, and not using medical




## 40C

## MAKING MEDICINES SAFER

Uppsala Monitoring Centre – 40 years of pioneering pharmacovigilance

safer medicines – safer use – safer patients



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WHO Collaborating Centre for International Drug Monitoring

## EXPECTING THE WORST

Anticipating, preventing and managing medicinal product and other healthcare crises



Theory and good practice guidelines for regulatory authorities, pharmaceutical companies, healthcare facilities and organisations, and national and regional pharmacovigilance centres





the UPPSALA MONITORING CENTRE

2nd edition completely revised and updated and with a new chapter on vaccines and crisis management

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## SIGNAL DETECTION FOR NATIONAL PHARMACOVIGILANCE CENTRES WITH SMALL DATA SETS

Uppsala Monitoring Centre



INSPIRE. ENGAGE. TRANSFORM.

## Annual report

July 2016 - June 2017

# UMC Website, Podcast and Social Media



## A global culture of patient safety

*Our ambition is to help make the world a better place for patients and their communities. Whether you are citizen, patient, scientist or professional, we hope you'll find something interesting and useful to you on the site. We're always pleased to hear from you; contact us [here](#).*



[www.who-umc.org](http://www.who-umc.org)

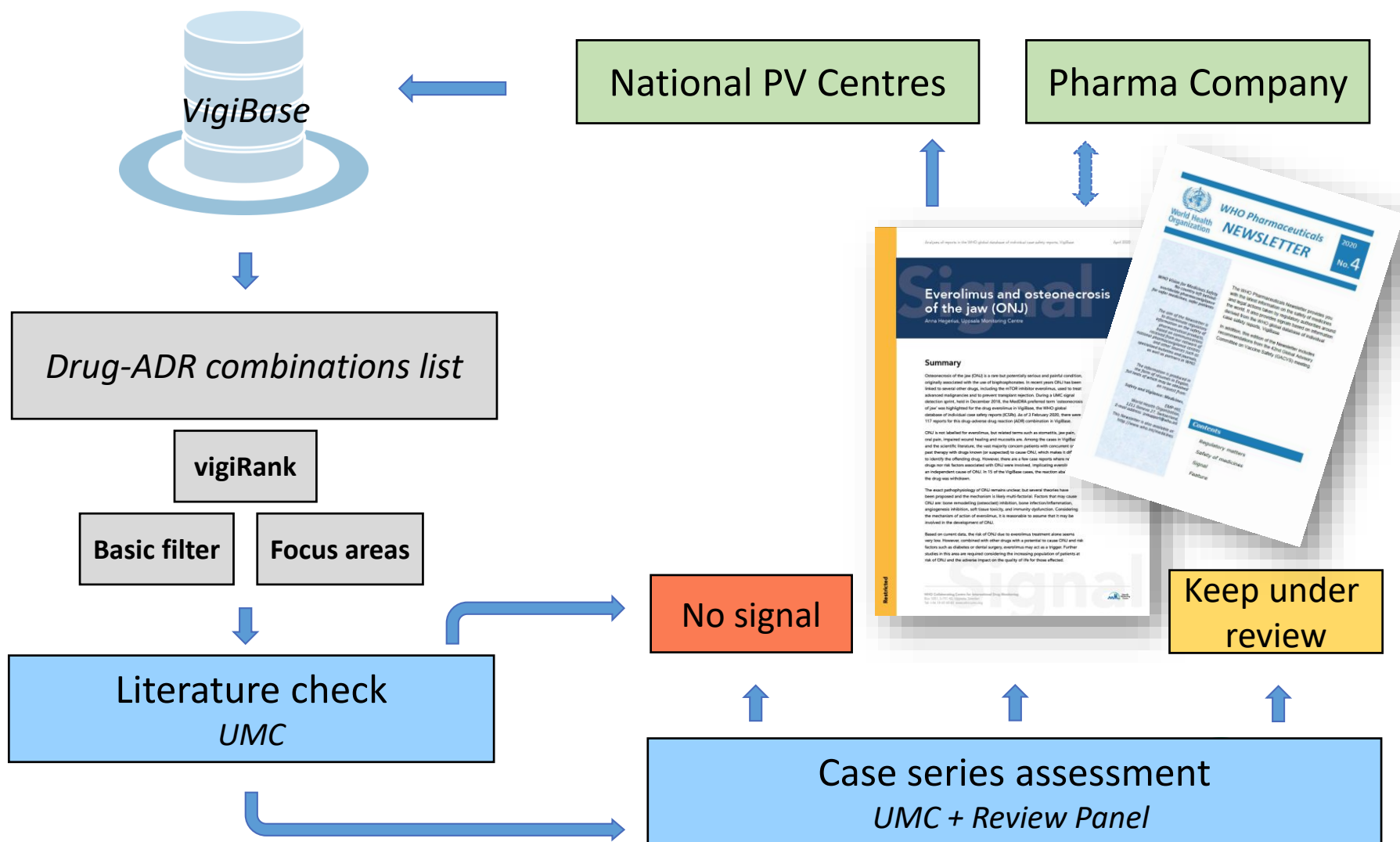


# Scientific Development

## Explore the risks and benefits of medicines, advancing the science of pharmacovigilance

- Signal detection and assessment
- Methodological research, e.g.
  - vigiGrade (report quality)
  - vigiMatch (duplicate detection)
  - vigiRank (statistical signal detection)

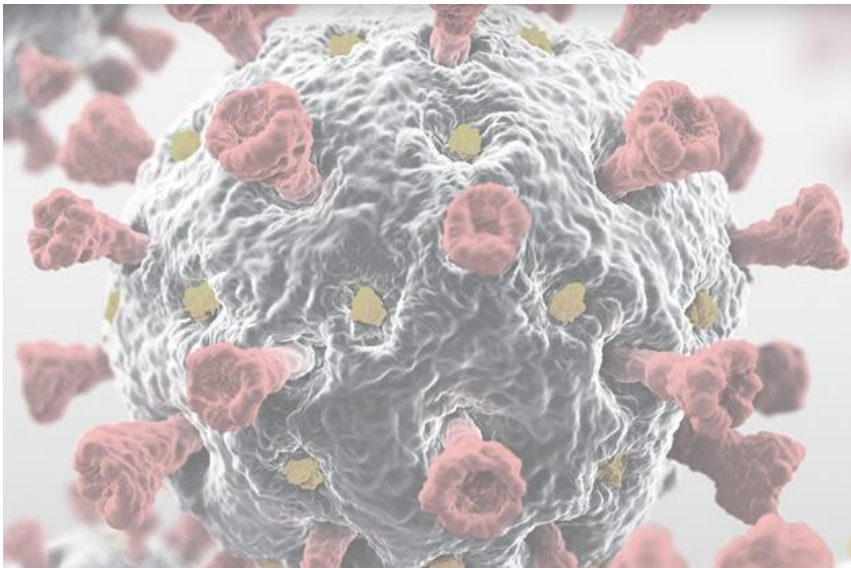
# UMC Signal Detection Process





# COVID-19 Treatment

- Drugs for COVID-19 are used off-label, repurposed or experimentally
- Unclear benefit-risk balance for COVID-19





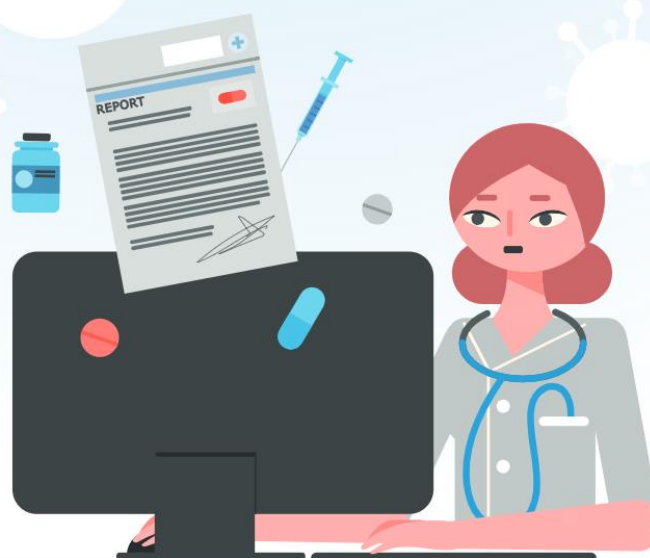
# Social Media

## COVID-19: reporting suspected side effects of medicines

### Help us understand how medicines act in COVID-19

We encourage **healthcare professionals** to report all suspected side effects their COVID-19 patients experience while infected, including with medicines intended to treat the disease or pre-existing conditions.

**Suspected side effects** should be reported even if the medicine is not authorised for use in COVID-19.



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# So, What Does UMC Do?

- COVID-19 working group
- Regular reviews on COVID-19-related ICSRs
- Shared on VigiLyze and by WHO
- Guidelines for coding and analysis
- [Paper on sex differences in reported ADRs](#)

Original Research Article | [Open Access](#) | Published: 25 September 2020

## Sex Differences in Reported Adverse Drug Reactions to COVID-19 Drugs in a Global Database of Individual Case Safety Reports

[Alem Zekarias](#) , [Sarah Watson](#), [Sara Hedfors Vidlin](#) & [Birgitta Grundmark](#)

[Drug Safety](#) (2020) | [Cite this article](#)

# Most Reported COVID-19 Drugs

Drug	N total
Hydroxychloroquine	2814
Remdesivir	2540
Azithromycin	1784
Lopinavir/Ritonavir	1154
Tocilizumab	669
Other	625
Chloroquine	448
Glucocorticoids	352
Heparins	267
Ivermectin	261
Favipiravir	226
Oseltamivir	187
Sarilumab	161
Unique reports	8643

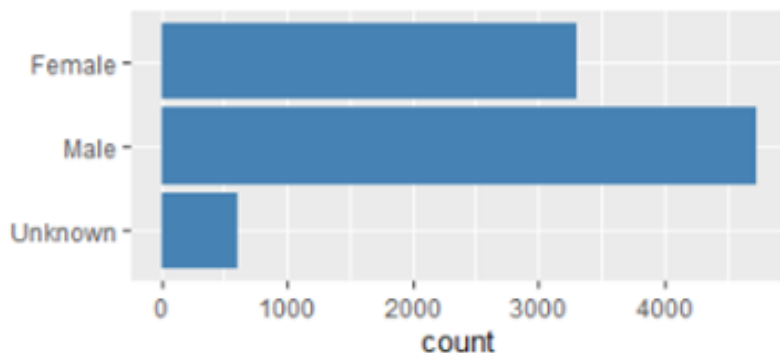
Reporting counts for all the drugs with 100 or more unique reports. N total includes reports received to Vigibase no later than the 4<sup>th</sup> of October.

Other drugs are selected from medical expertise from the set of corona virus indicated drugs reported to Vigibase.

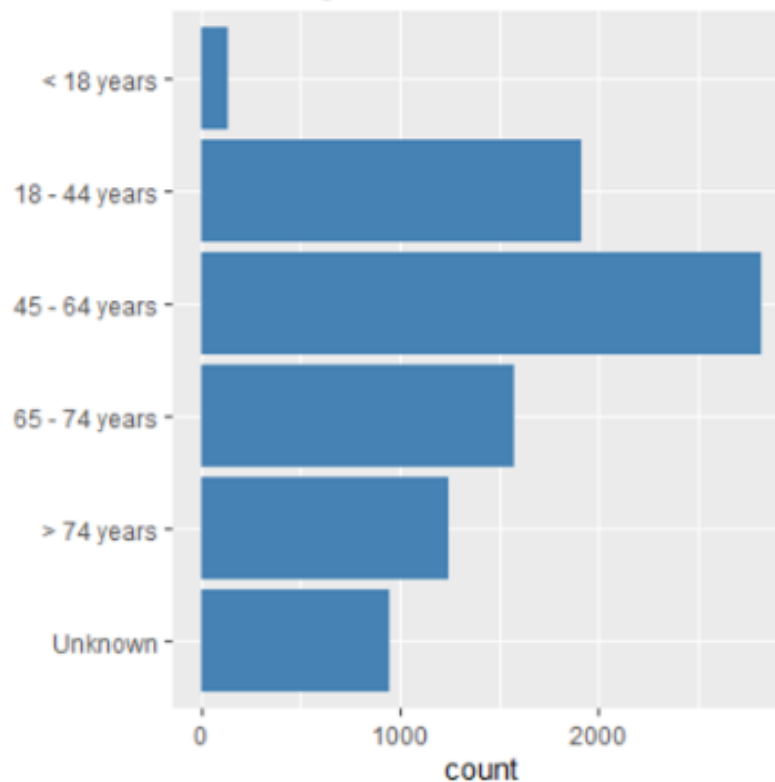
Counts include suspected or interacting drugs. As one report may contain several drugs, rows are not mutually exclusive.

# Patient Characteristics

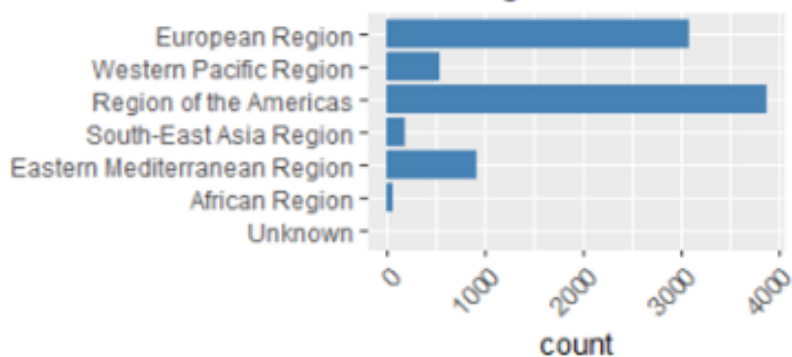
Patient sex



Patient age



WHO region



# Roll-out of Covid-19 Vaccines

- Analytical approaches for the global data
- Advocacy for use of global data and minimised lag time in this situation
- Adapting the PV products
  - **VigiFlow** will be equipped with fit-for purpose data entry and local/national analysis support
  - **VigiLyze** will get improved search for vaccines and disproportionality calculations at levels appropriate for analysis of these vaccines

# Thank you for your attention!



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