Uppsala Monitoring Centre
Making Medicines Safer

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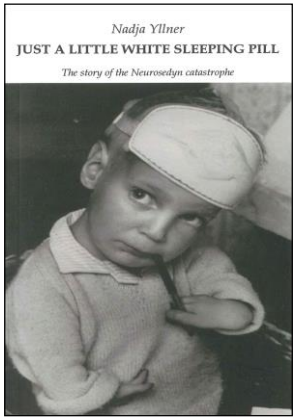
WHO Programme for International Drug Monitoring



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

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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.

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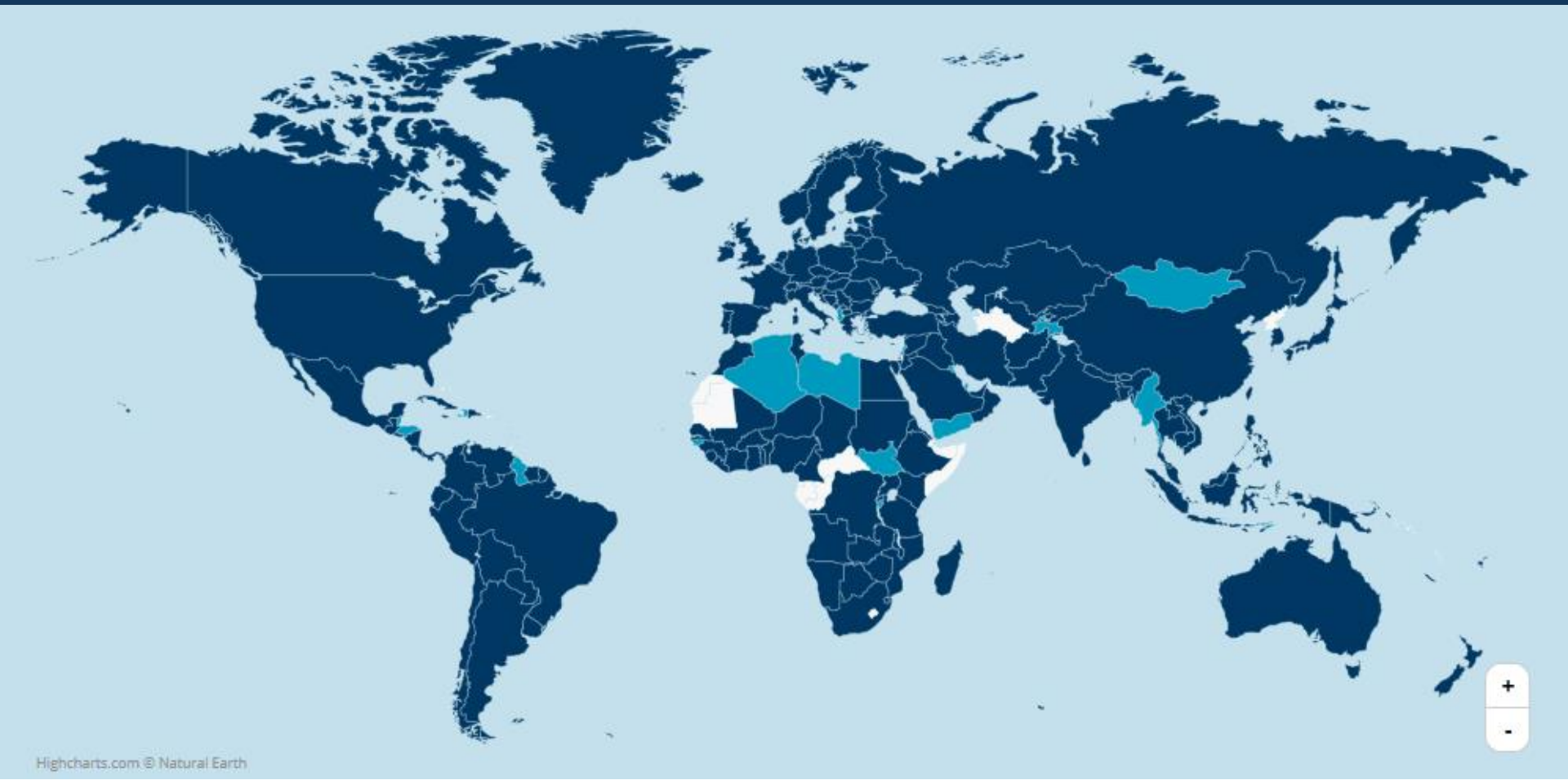
WHO PIDM Member Countries (Oct 2020)



Full members: 140
Associate members: 30
Total: 170

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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

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PV Stakeholder Overview

WHO-CC Morocco CAPM

WHO-CC India PvPI-IPC

WHO-CC Norway FHI

WHO-HQ Switzerland Geneva

National PV Centres Regulators

WHO-CC Sweden UMC

Pharma industry

Healthcare

Patients The public

Public Health Programmes

Academia

Health Organizations

Donors

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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

Portfolio Management

Customer Engagement

IT Development & Operations

Pharmacovigilance Science

Legal

Pharmacovigilance Products

Pharmacovigilance Products Support

Product Management

Data Science

Licence Coordination

WHODrug Products

Content Management & Support

Product Management

Education & Training

Finance & Core Services

Products & Services

Research & Education

Human Resources

Global Outreach Secretariat

Global Communications

Director

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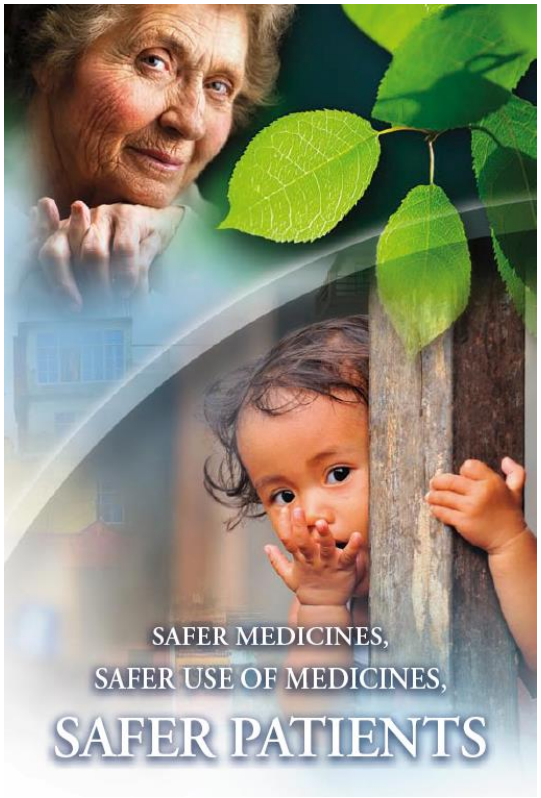
UMC Vision and Mission



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

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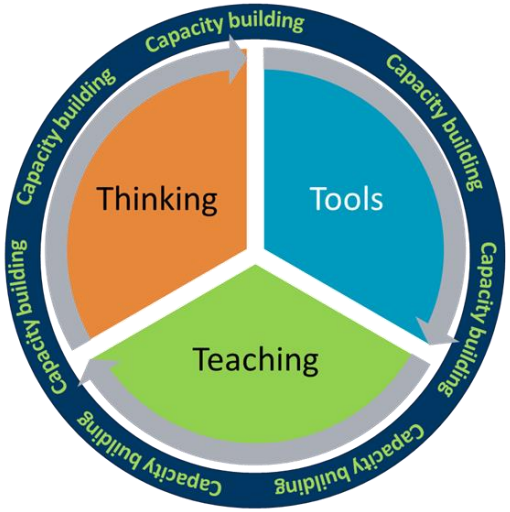
Work Areas

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



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Provision of Technology and Support Tools

PV tools

- VigiFlow
- VigiLyze
- VigiAccess

Clinical information

- VigiBase

Dictionaries and terminologies

- WHODrug Global
- (MedDRA)

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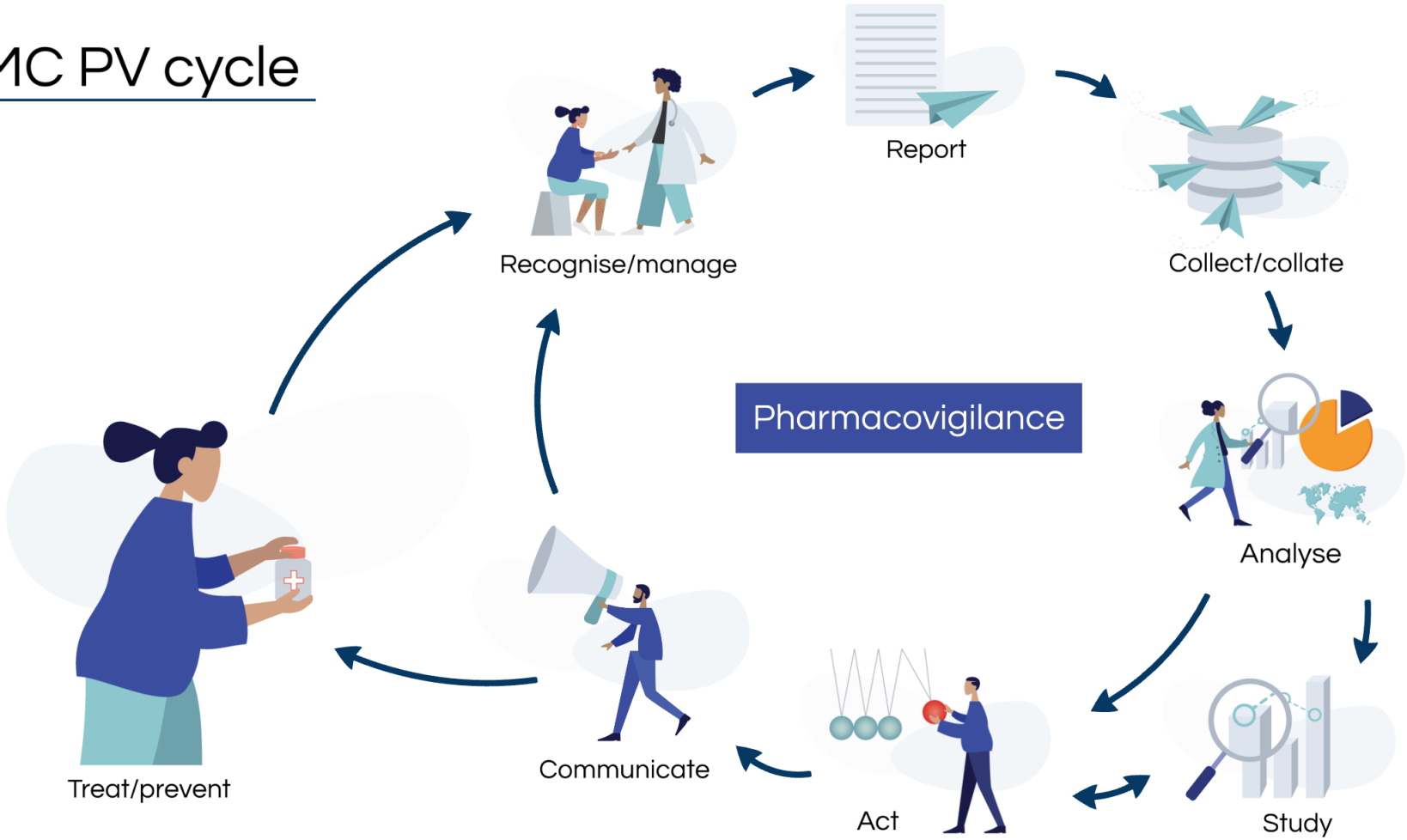
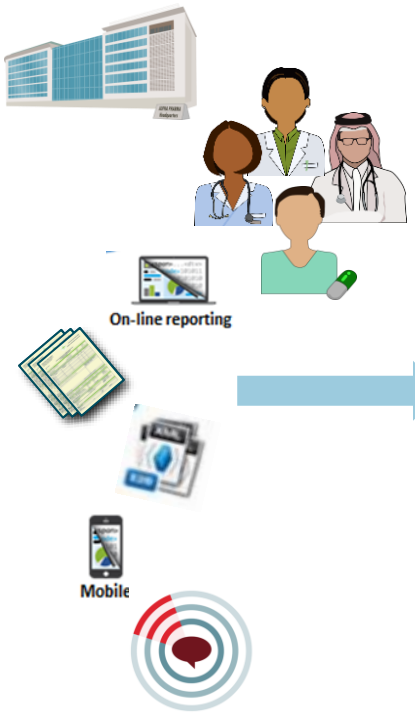
UMC PV cycle

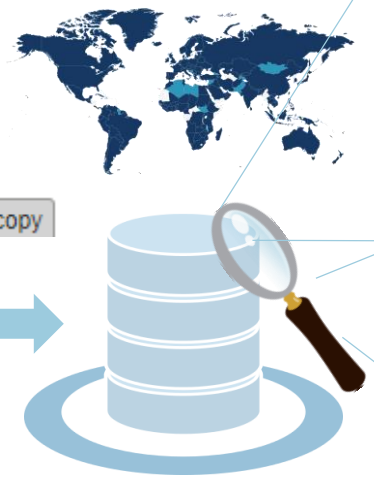

Report
Recognise/manage
Collect/collate
Pharmacovigilance
Analyse
Treat/prevent
Communicate
Act
Study

The Flow of ICSRs

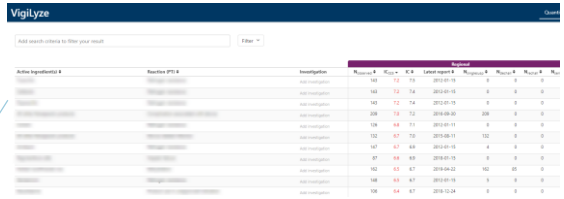


VigiFlow
National
ICSR database

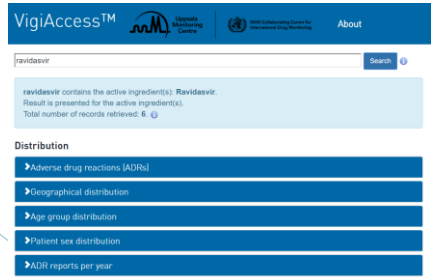
Send copy



VigiBase
WHO Global
ICSR database



VigiLyze
Search and signal management



VigiAccess.org
Search and statistics

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VigiFlow – ICSR Data Management

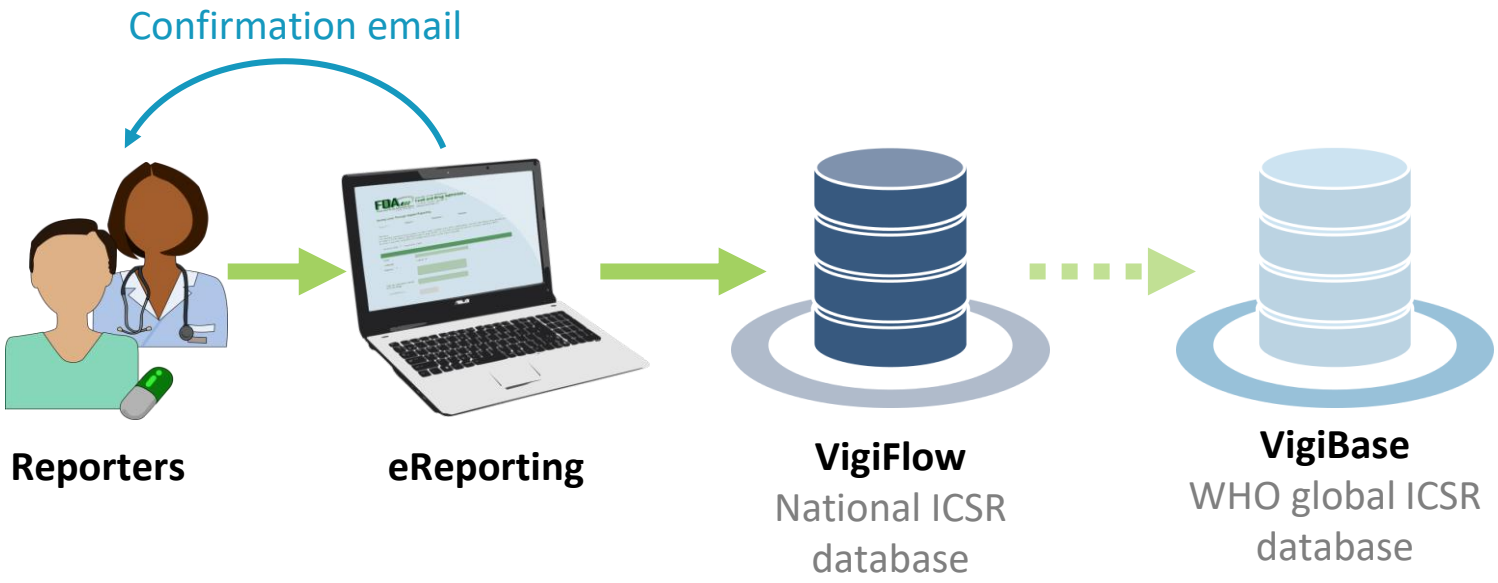
- Collect, process, analyse and share ICSRs
- Web based and ICH E2B compliant
- WHODrug/MedDRA
- ADRs and AEFIs*
- For national (and regional) PV centres

*AEFI = Adverse Event Following Immunization

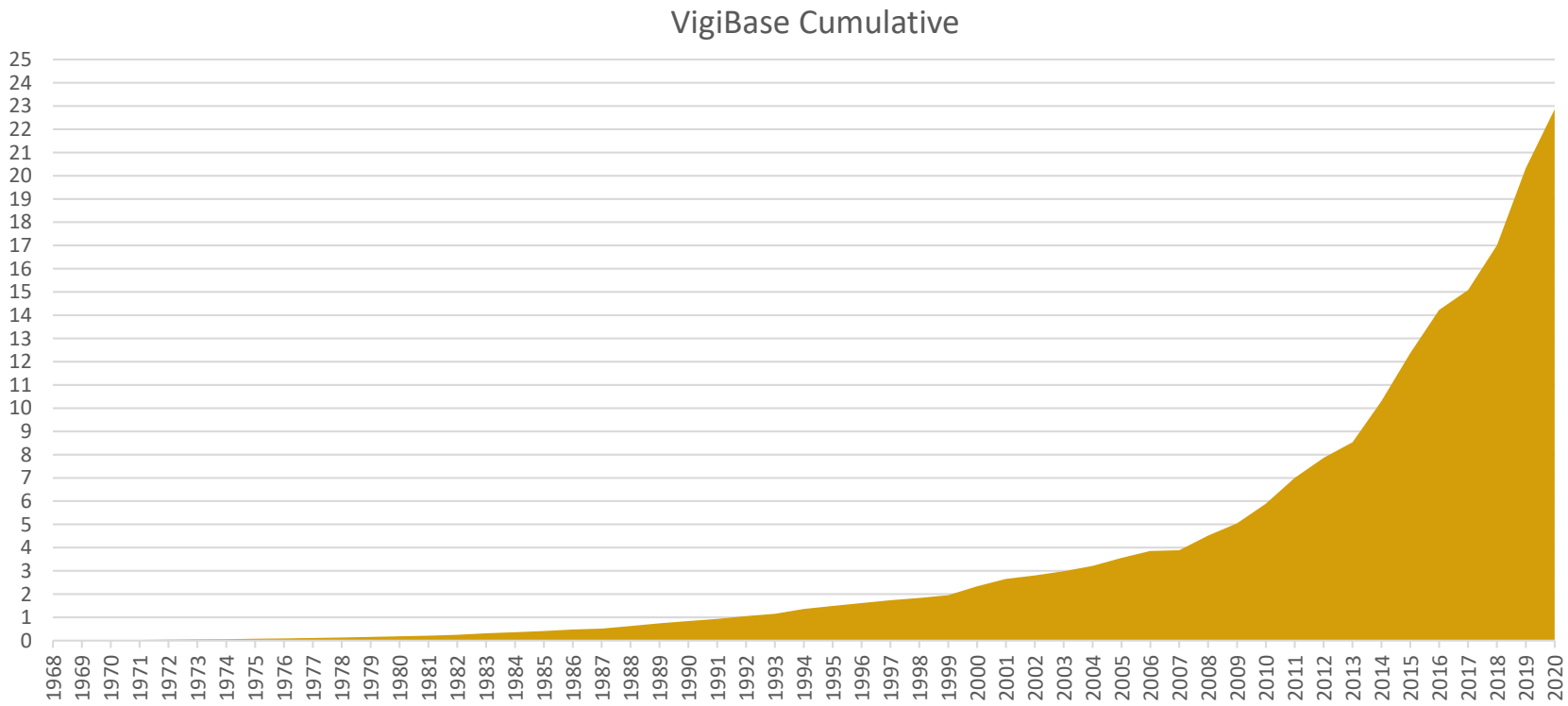
eReporting – An add-on module to VigiFlow

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)

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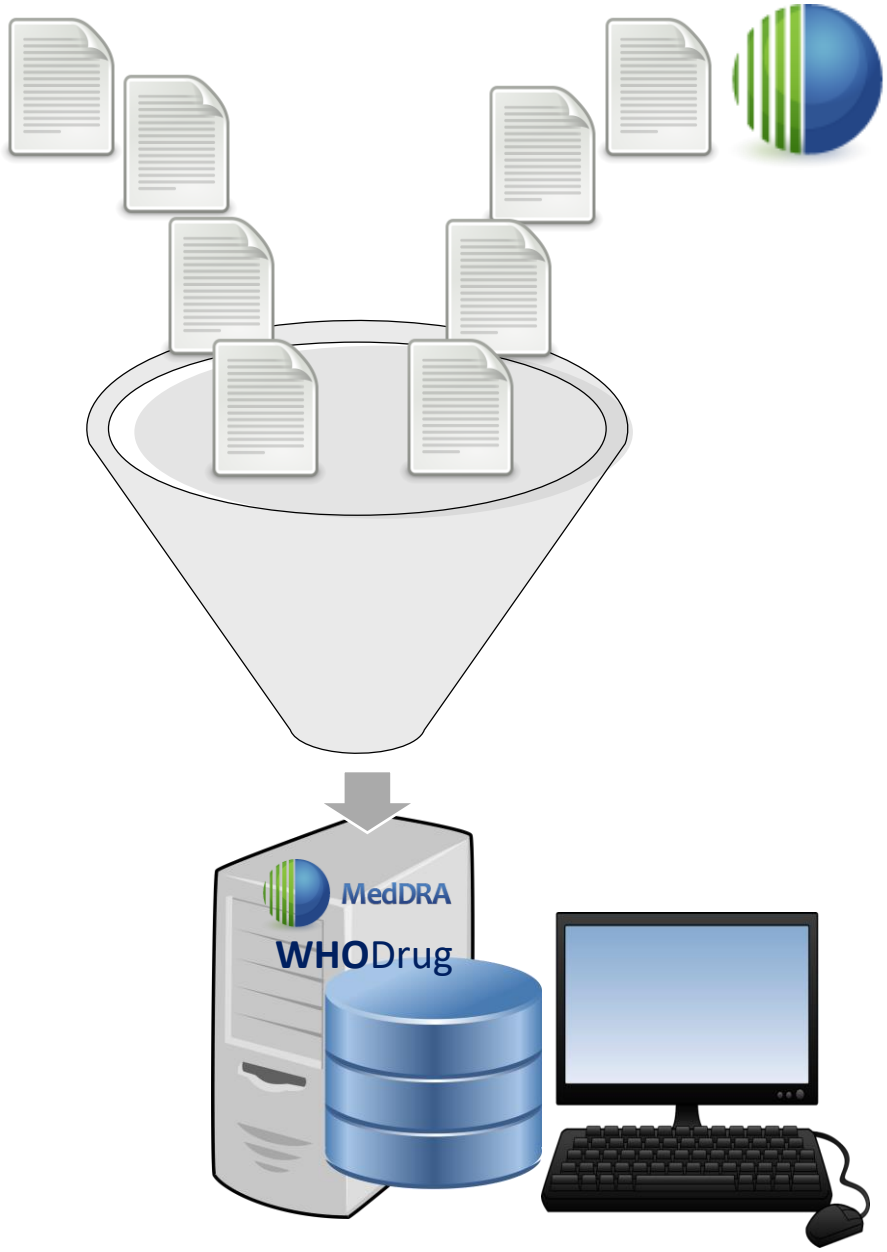
Status as of June 2020

WHODrug

MedDRA



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WHODrug Global

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

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VigiLyze – Signal Management

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

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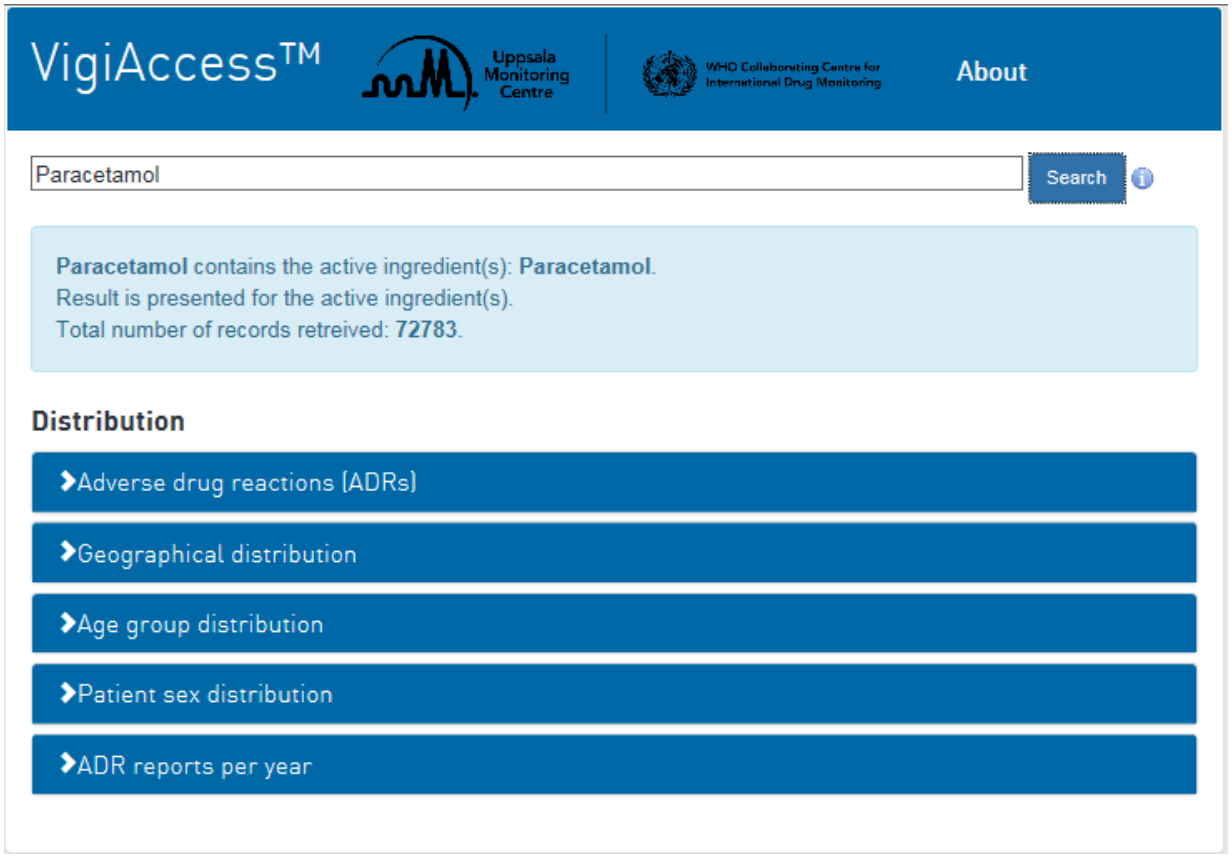
VigiAccess – For the Public



www.vigiaccess.org

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Training Offerings

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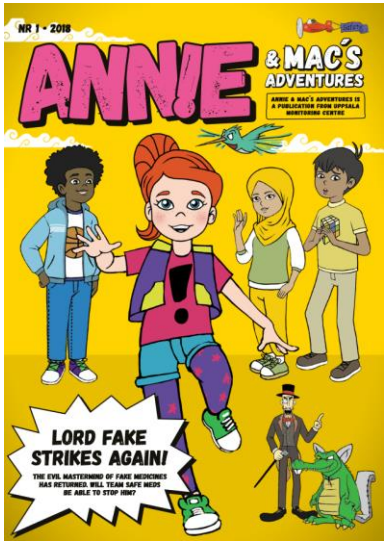
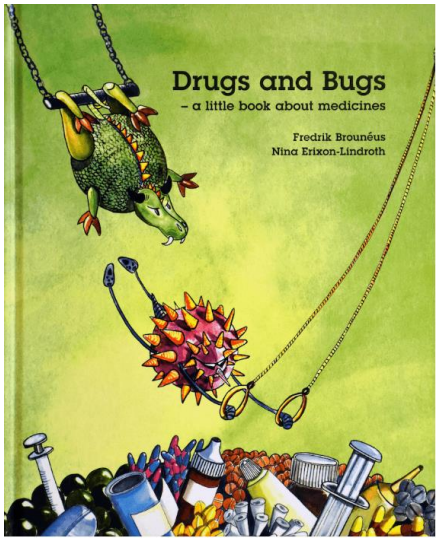
Advocacy - Raising PV Awareness

take & tell
Together for safer medicines





https://youtu.be/89lwQmddQrQ

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Uppsala Reports

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UMC Publications

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

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)

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UMC Signal Detection Process

National PV Centres

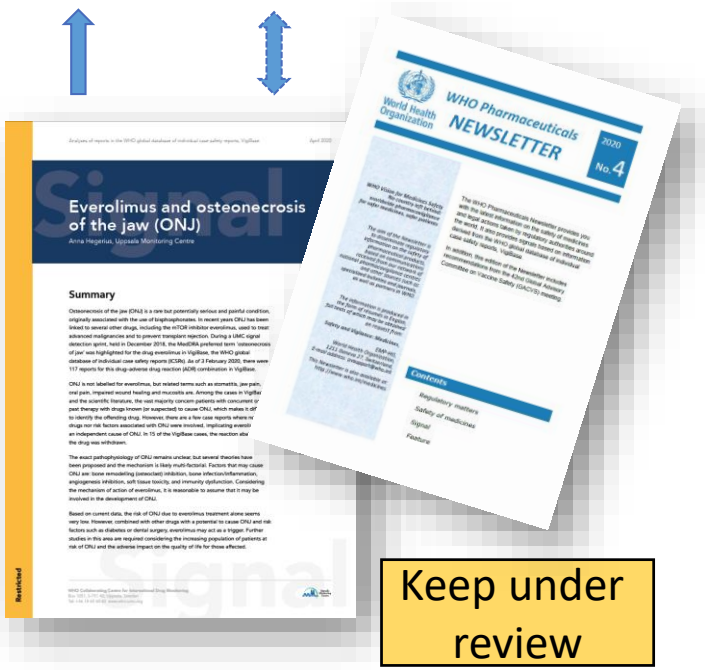
Pharma Company

Drug-ADR combinations list

vigiRank

Basic filter

Focus areas



No signal

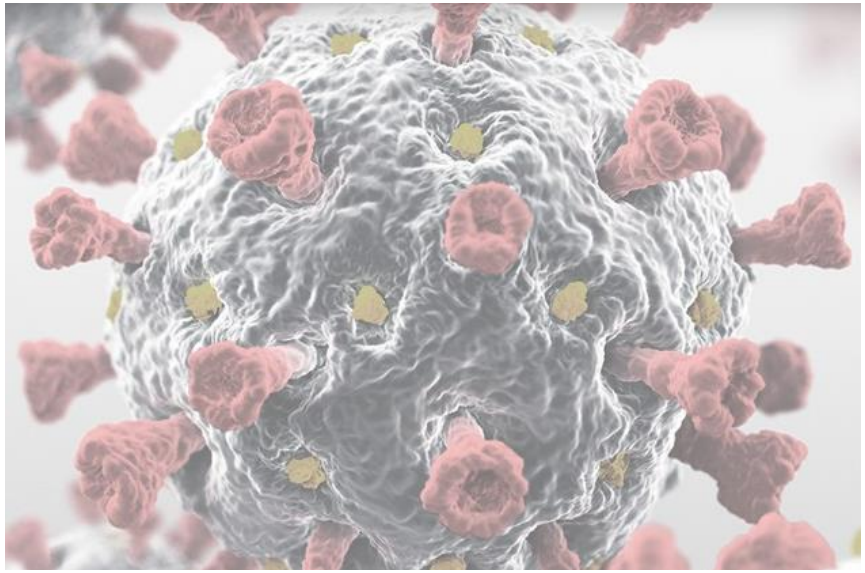
Keep under review

Literature check
UMC

Case series assessment
UMC + Review Panel

COVID-19 Treatment

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



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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

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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

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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 4th 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.

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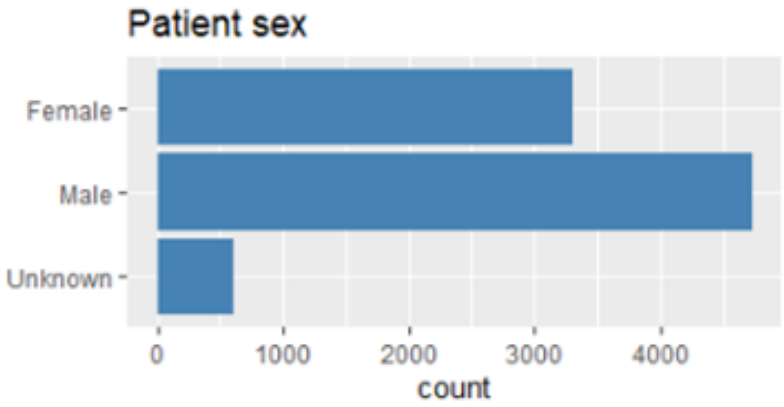
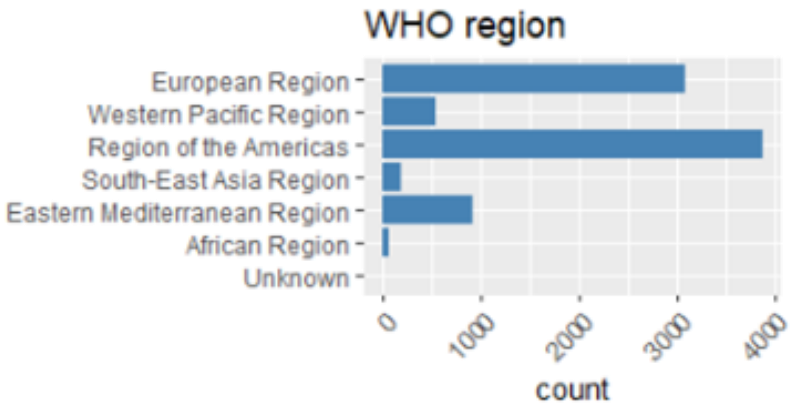
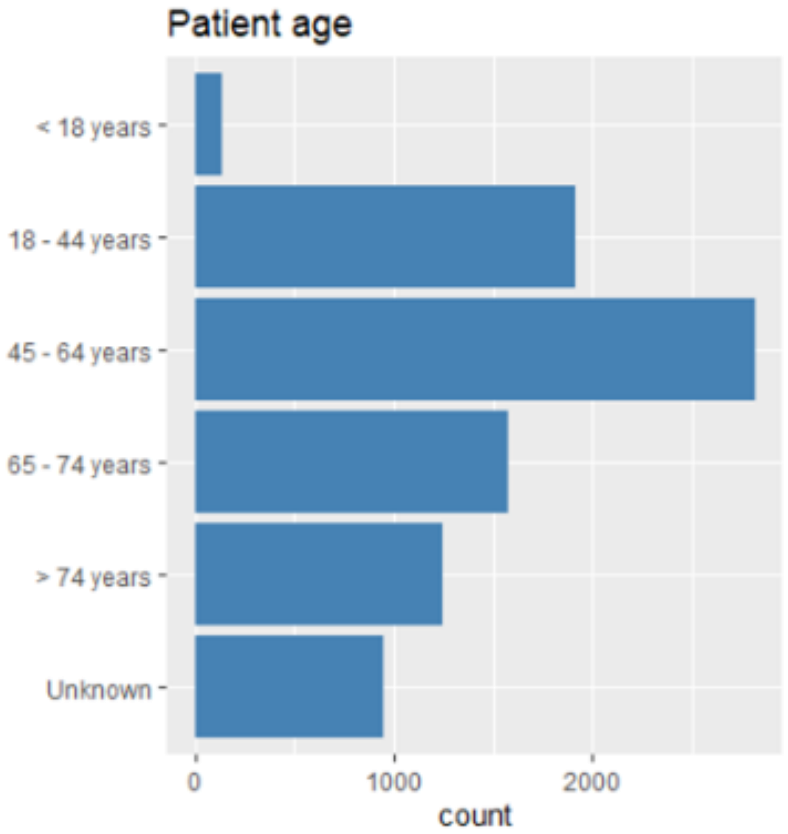
Patient Characteristics







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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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