Uppsala Monitoring Centre

Annual report
July 2019 - June 2020

The year in review

July 2019–June 2020

Foreword by the director

This year has been nothing like "business as usual", and my last year in charge of UMC will certainly stay in my memory for as long as I live.

When the coronavirus pandemic hit, ensuring safe working practices for staff so that we could maintain all vital UMC functions and continue to support the pharmacovigilance community in the best possible way took priority. I appointed an internal COVID-19 task force to review all ongoing activities in the light of the pandemic, and to come up with proposals for actions and initiatives that we should undertake to support global efforts to identify and monitor the safety of potential treatments. As a result, there have been more changes in priorities compared with previous years. We were very sorry to have to postpone our annual training course and the Uppsala Forum conference, as well as cancel all physical meetings. And some of the planned improvements to our tools and services may be delayed. But on a positive note, we found that our webinars and other virtual training and teaching sessions have been very well attended and appreciated. Hopefully, as coronavirus subsides, we will continue to make full use of modern technology as a useful and efficient accompaniment to face-to-face meetings. Our education and training team are now developing both the curriculum and the delivery channels to meet the needs of a post-pandemic society.

Our key priorities for the remainder of 2020 and 2021 are to do signal detection and analysis related to COVID-19 treatments, including vaccines as they become available. There will be two major themes: continued examination and regular summary reports of all VigiBase data relating to COVID-19 treatments; and the development of syndromic detection methods to quickly identify emerging harm from new treatments, with particular focus on vaccines. Our ambition is to complement other efforts and as far as possible keep a global perspective.

In order to achieve good results, we have to ensure that timely and relevant data reaches VigiBase. This is not something we can do on our own, and I would like to extend my warmest thanks to our colleagues in national pharmacovigilance centres who have responded quickly and positively to our call for help.

Another important development is to adapt VigiFlow and VigiLyze to optimise reporting and analysis of COVID-related data. Speed and detection sensitivity are critical, particularly in a scenario where millions of people will get new types of vaccines, and we cannot rely solely on spontaneous reporting systems to provide the data that is needed to promptly identify emerging signals of safety problems. Here we are working closely with WHO headquarters to establish a flow of data to VigiBase also from public health programmes.

Finally, a few words prompted by my retirement in November 2020. Little did I know that autumn day 41 years ago, when I got a job at the WHO Collaborating Centre for International Drug Monitoring, that it would be the start of a lifetime in pharmacovigilance. Apart from a brief stint at the Swedish national pharmacovigilance centre in the 1980s, I have spent my working life serving the WHO Programme for International Drug Monitoring. It has been a privilege to be part of this international collaboration, to help the network grow and mature, to meet so many fantastic, hardworking people across the globe, and to know that I have played a role in a vital scientific endeavour. And quite a lot of fun, too!

Marie Lindquist pictured with her successor Hervé Le Louët, the new CEO of UMC from November 2020

Handing over the helm to my successor, **Hervé Le Louët**, I'm confident that the spirit of collegiality and friendship within the pharmacovigilance community will make his job as rewarding and enjoyable as it has been for me.

Marie Lindquist
Director

Highlights of the year

UMC published **20 safety signals** in VigiLyze

Analyses and studies were performed **in response to COVID-19**

A paper evaluated the **robustness of disproportionality analysis in smaller databases**

A paper described methods **to detect signals in risk groups** consisting of the elderly, males, females, underweight people, obese people, and patients from Asia

Two research collaborations with Japan and its medicines agency were carried out

A pilot study was made, investigating **patients' expectations of pharmacovigilance and information in VigiBase**

The Chinese language version of **WHODrug Global** was made available in September 2019

The **old version of VigiFlow** was closed after all safety information migrated to the new VigiFlow

The new e-learning course, **"Introduction to pharmacovigilance"**, was released in English and Spanish

Four MSc thesis projects were carried out at UMC

UMC's podcast **Drug Safety Matters** went on air, providing a platform for in-depth interviews

13 WHODrug webinars were given, covering new functionality, SDGs, Koda, WHODrug Global Chinese, and coding challenges

UMC contributed to **13 training initiatives** in Africa, Latin America, Asia and the Mediterranean region

The online version of Uppsala Reports launched: **www.UppsalaReports.org**

Pharmacovigilance resources

UMC provides resources for pharmacovigilance practice via access to information as well as tools and services for WHO programme members and the wider pharmacovigilance community. This allows countries to transform data into improved clinical practices. UMC develops and spreads knowledge on scientific methods and best practices and provides guidance on the use of data management and analysis tools.

WHODrug

Combining comprehensive drug information and powerful analytical tools, WHODrug Global is the world's most widely used drug dictionary. In September 2019 a **Chinese language version of WHODrug Global was launched**; updates continued during the year, and it was integrated into the WHODrug Insight search tool. In May 2020 the Chinese Center for Drug Evaluation issued a draft guidance on the submission of clinical trial data; WHODrug Global Chinese is compliant with the CDISC SDTM standard. WHODrug Global Chinese is also available as both fixed width text files and in .csv format.

More progress was made with the automated coding tool **WHODrug Koda**. WHODrug Koda supports the drug coding process by effectively providing both drug name coding and ATC coding. The ATC selection model for WHODrug Koda was further refined in March 2020, to make the selection of ATC codes even more specific in scenarios with two or more similar ATC codes.

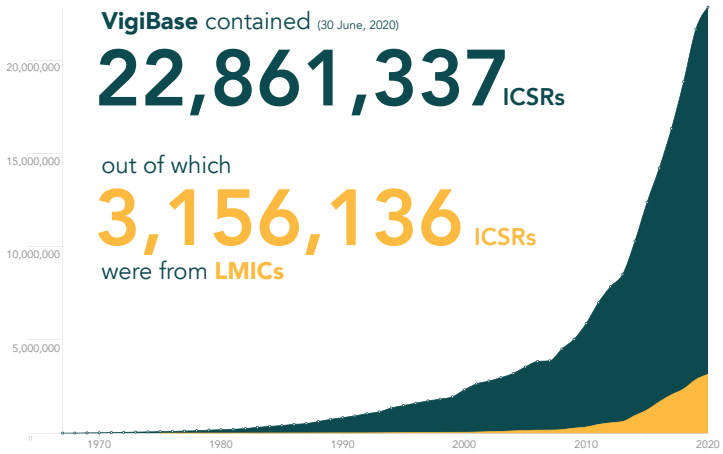
Every day, some **20,000 searches were made in WHODrug Insight**, the most common being for drug names, and improvements have been made to speed these up. WHODrug Insight was further enhanced with a new algorithm, highlighting the most commonly sought drug names.

With face-to-face meetings put on hold due to the COVID-19 pandemic, WHODrug User Group meetings moved online. The first **webcast** aired in April 2020 and replaced the meeting in Amsterdam. WHODrug webinars also continued apace. And a video produced in-house featuring the WHODrug team showed how it **collects, validates and classifies drug information** from multiple international sources.

VigiBase

VigiBase is the WHO global database of individual case safety reports (ICSRs). It is the largest database of its kind in the world and contains reports of suspected adverse effects of medicines. Member countries of the WHO Programme for International Drug Monitoring have been submitting reports since 1968. The number of ICSRs in VigiBase **increased from 20 million to almost 23 million** at year end. The number of ICSRs in VigiBase from low- and middle-income countries was **3,156,136** and now constitutes 13.8% of all ICSRs in the database.

WHODrug hosts in the studio for the WHODrug User Group Webcast China



VigiBase cumulative increase and ICSRs from LMICs in VigiBase, as of 30 June 2020

Of the 140 full member countries, 134 submit reports in ICH E2B format, of which 104 were compliant with the latest version of E2B(R3), and 30 used E2B(R2); in comparison with 14 in our last report, there are now only 6 countries using other formats for ICSR transmission.

VigiLyze

UMC has a dedicated support team helping organisations apply best practices for VigiFlow and VigiLyze to national pharmacovigilance processes and regulations. As the tools are intended to work alongside local processes, there is no one-size-fits-all solution; they have to be adapted to the specific setting, at a distance, via web-based teleconferences and webinars. Web-based, accessible and user-friendly, VigiLyze has become an information hub as well as a search and analysis tool during COVID-19.

VigiFlow

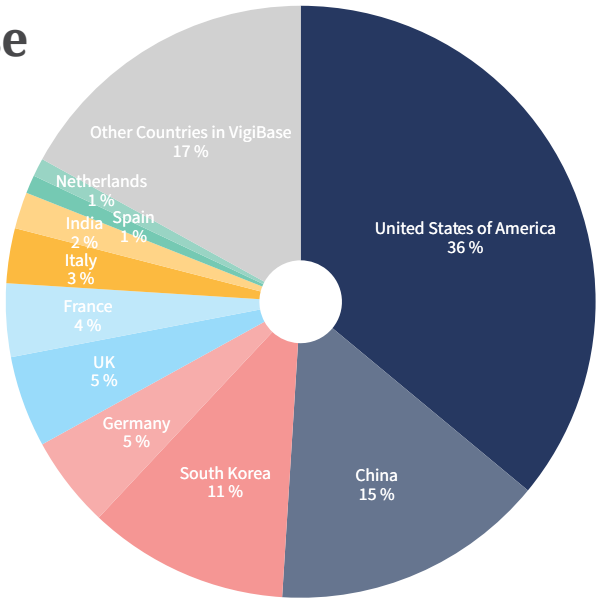
UMC further developed VigiFlow into a system that supports the day-to-day pharmacovigilance work at national and regional pharmacovigilance centres. Compliance with the latest international standards and improved functionality were needed, and in early June 2020 all countries were moved to the new version of VigiFlow. The migration from the old to the new system was a major undertaking and saw centres work closely with UMC to "clean up" their data to upgrade it to the latest international standards. This was all done to a tight time frame to avoid any disruption. Of the 170 members in the WHO programme, over 90 used VigiFlow either wholly or as part of their pharmacovigilance system at year end.

Regulatory obligations on market authorisation holders can be facilitated by importing digitised ICSRs into VigiFlow. Work began on an additional eReporting service for domestic and international pharma industry to submit data to national centres using VigiFlow, with launch planned for Q2 2021.

Additional statistics from VigiBase

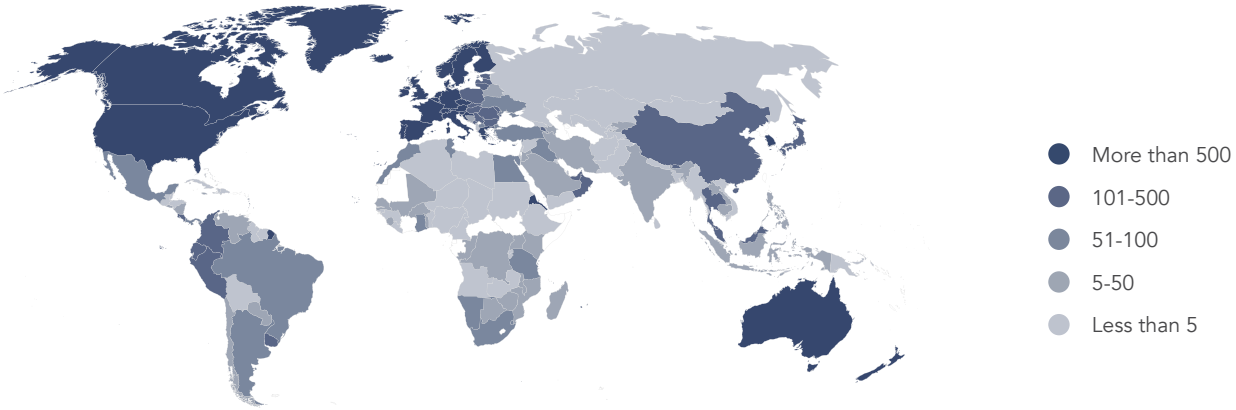
Country distribution for ICSRs received over the year

Country distribution in VigiBase for ICSRs received during the past 12 months, as of 30 June 2020



ICSRs per million inhabitants

ICSRs received in VigiBase 2015-2020 (average to compensate for year-to-year fluctuations)



Research, signals and methodology

A busy year for signals, publication of UMC signal detection methodology, and further research on de-identification, alongside an expansion of e-learning.

The detection of medicines safety signals is a core activity of UMC, and over the year **20 signals** were published in VigiLyze for use by national pharmacovigilance centres. These included several earlier signals that had been kept under review for additional data, as well as one of bradycardia with fluorouracil from the Latin America signal detection workshop in 2019. Signal assessments from selected national centres, including Netherlands and Eritrea, were also shared via VigiLyze.

UMC produced four scientific publications informing the practical signal detection work. One evaluated **the robustness of disproportionality analysis in smaller databases**, which indicated that disproportionality analysis is computationally robust for countries with as few as 500 reports, whereas for data subsets in general, a minimum of 3,000 to 5,000 reports may be recommended. This was followed by the publication of a guidebook, "**Signal detection for national pharmacovigilance centres with small data sets**".

Another paper described **the development and evaluation of methods to detect signals of risk groups for adverse drug reactions in VigiBase**. Seven signals describing previously unrecognised potential risk groups were communicated, related to elderly, male, female, underweight, obese and and patients from Asia.

A manuscript which presents the **theoretical basis for the method and includes an assessment of the stability and the clinical coherence of the identified patterns** was submitted for publication, and subsequently published in Drug Safety in July 2020.

Birgitta Grundmark gave a presentation on 'Strengthening the capacity for signal detection and management for pharmacovigilance national centres' in Bogotá, Colombia at the annual ISoP meeting

A paper was published about an initiative with the Netherlands Pharmacovigilance Centre Lareb and the Dutch thyroid patient organisation Schildklier Organisatie Nederland (SON) to communicate **a signal of panic attacks with levothyroxine directly to patients**. This generated considerable engagement resulting in additional patient experiences being received, further strengthening the original signal. Finally, a paper was accepted for publication that described **development and evaluation of methods to detect signals of drug-drug interactions in VigiBase**. Method development is a central part of UMC's research work: questioning how signal detection may best be performed, testing the algorithms we apply, pushing the boundaries of how data is used. A systematic evaluation of UMC's adverse event cluster analysis algorithm was completed. Previously derived vector representations for drugs and adverse events were made available for internal use and evaluation. They may offer an approach to identify semantically similar drugs and adverse events based on reporting patterns in VigiBase.

During the year an algorithm was evolved for identifying reports with outlying doses, which uses the overall reported doses of the same drug in VigiBase as reference. A signal detection sprint with the WHO Collaborating Centre in Rabat, Morocco, then explored its use to detect reports related to possible medication errors not explicitly coded as such. It found that there was rarely enough information in narratives or the structured information of such reports to support the required assessment – possibly because most reports where the reporter has reflected on an outlying dose related to a medication error have been coded as such.

An **evaluation of Japanese reporting patterns in VigiBase** highlighted a higher proportion of well-documented reports, reports submitted by physicians, and reports with just a single adverse event term as key features. A paper was accepted for publication that assesses **the impact of regulatory actions and reporting patterns of interstitial lung disease in Japan**. A **Letter to the Editor in *World Psychiatry*** cited analyses of VigiBase to better describe and understand the impact of pneumonia as a suspected adverse reaction to clozapine. Another UMC paper described **the use of VigiBase combined with longitudinal observational health data in the assessment of a signal for colitis with nintedanib**.

Research, signals and methodology

UMC's Research team forge strong collaborations with individuals and groups internationally to further the science of pharmacovigilance. The completed IMI WEB-RADR project, which sought to utilise and evaluate social media and mobile reporting technologies for pharmacovigilance purposes, produced three further papers: the first **the evaluation of adverse event recognition in Twitter and Facebook**, exposing the difficulties in implementing automatic adverse event recognition in Twitter, and warning of discrepancies between published performance evaluations and observed results for independent data; the second **a benchmark performance evaluation reference set for adverse event recognition in Twitter**; and the third the project's **final recommendations for use of social media in pharmacovigilance**.

The Consortium for Advanced Research Training in Africa (CARTA), of which UMC is a member, pioneered a new concept for stimulating and funding joint research in pharmacovigilance involving both academia and national pharmacovigilance centres in Africa which yielded several applications. UMC also contributed to 13 training initiatives in Africa, Latin America, Asia, and the Mediterranean region, including causality assessment and signal detection, using the tools VigiFlow and VigiLyze.

The collaboration with the UK's Medicines and Healthcare products Regulatory Agency (MHRA) to develop and evaluate methods for de-identifying free text case narratives intensified: a study protocol was approved; data from the Yellow Card Scheme obtained; and algorithms consolidated in preparation for the next phase of the study later in 2020. A pilot study was completed which focused on patients' expectations on pharmacovigilance and whether information in VigiBase can provide answers to some of their questions.

Four MSc thesis projects were carried out at UMC, by students from universities in Uppsala and Stockholm. These were "Retrospective disproportionality analysis to investigate the usefulness of the WHODrug Standardised Drug Groupings in the pharmacovigilance signal detection process", "Extracting adverse drug reactions from product labels using deep learning and natural language processing", "Improving the speed and quality of an adverse event cluster analysis with stepwise expectation maximization and community detection", and "Normalization of adverse event verbatims to MedDRA".

Jennifer Wall and other UMC staff provided training on VigiFlow and VigiLyze at the national centres meeting in Bogotá

UMC portfolio of scientific methods

vigiRank: Predictive model that ranks pharmacovigilance safety signals according to multiple aspects of strength of evidence.

vigiMatch: Probabilistic record-matching method to detect unexpectedly similar pairs of records in a database.

vigiGrade: Multidimensional measure of data quality in pharmacovigilance (completeness, relevance, consistency, etc.).

vigiPoint: Algorithm to pinpoint the key features of a subset of database records in contrast to a broader set.

vigiTrace: Suite of analytics methods for the analysis of longitudinal event history data, including chronographs for statistical graphical overviews and the calibrated self-controlled cohort design for temporal screening.

Communications and awareness

UMC continues to take the lead in the promotion of good pharmacovigilance practice and advocacy of better communication, to improve patient safety around the world.

In its 25th year, Uppsala Reports took a big step forward with the launch of an online news site: **UppsalaReports.org**. This new "web first" publishing strategy means that articles are published regularly online, allowing for more timely reporting of recent events. The new website attracted more than 5,500 visits in its first two months; the standard newsletter was sent to 7,000 digital subscribers; and hard copies of two issues were posted to all national pharmacovigilance centres.

Drug Safety Matters, UMC's podcast on pharmacovigilance and patient safety, launched in January 2020. Through in-depth interviews with experts in the field, the show seeks to shed light on the latest trends and new challenges in medicines safety. Five episodes aired and almost 900 downloads had been recorded by June.

UMC's social media channels grew steadily with over 31,100 followers across LinkedIn, Facebook and Twitter – an increase of over 10,000 (50%) from the previous year. Continuous updates were made to UMC's website who-umc.org, which saw a 41% year-on-year increase in traffic (191,000 visitors in total), with a focus on WHODrug, recruitment, online education, and communications.

UMC coordinated the annual social media campaign **#MedSafetyWeek** for the third time in November 2019, and invited the WHO Programme for International Drug Monitoring network to participate: 61 countries' regulatory agencies took part, compared to 32 the previous year. The agencies shared three animations, adapted to their local language, with the regulator's logo. The films reached over 6 million people on Twitter alone and were viewed 10 million times across the globe.

Bob Allkin discusses the regulation of medicinal plant names in episode #3

The mini-documentary "**Signal detection in Latin America**" was shown at the annual meetings of the WHO Programme for International Drug Monitoring and the International Society of Pharmacovigilance, in Bogotá, Colombia in autumn 2019.

The communications department produced **11 eye-catching research posters** for conferences. An oral presentation and poster on the 2018 **MedSafetyWeek** campaign were presented at the ISoP meeting in Colombia. Communications staff gave presentations at the Asia-Pacific pharmacovigilance course in Ghaziabad, India, and the European medicines regulatory network Heads of Medicines Agencies' Working Group of Communications Professionals in Oslo, Norway.

The two issues of UMC's comic book Annie & Mac's Adventures were translated into Spanish and Russian, and at the request of the Colombian regulator INVIMA, customised versions were created.

Building capacity

As a WHO Collaborating Centre, UMC supports WHO's overall strategies for pharmacovigilance capacity building. Education and training in pharmacovigilance concepts and thinking are central to this.

UMC staff provide technical and operational support and guidance to the member countries of the **WHO Programme for International Drug Monitoring**, particularly countries which recently joined the programme. During 2019-2020 the programme welcomed **Luxembourg** (an associate and full member in 2020), **St Vincent and Grenadines**, **Nicaragua**, **Dominican Republic** (an associate in 2020, it became the 140th member in June 2020) and **Belize**. Organisations joining the programme are given an introduction to all of UMC's pharmacovigilance tools.

UMC has supported the roll-out of the **MedSafety mobile app** to boost ADR reporting in seven countries in collaboration with WHO and the MHRA. The medicines lists from these countries were quality assured before including them in the app. This flowed from the WEB-RADR 2 project, which sought to build on the functionality of the app developed in the original WEB-RADR project sponsored by the Innovative Medicines Initiative.

For the WHO-led Smart Safety Surveillance (3-S) project to help low and middle-income countries identify, assess, and adequately manage the risks associated with new products, UMC conducted VigiFlow and VigiLyze training sessions as part of courses organised by WHO in Ethiopia and Thailand. When Mexico began to use VigiFlow and VigiLyze as part of its national and regional systems in the autumn of 2019, UMC held on-site training to ensure successful implementation.

UMC contributed to 13 training initiatives in Africa, Latin America, Asia and the Mediterranean region, in topics including causality assessment and signal detection, using UMC's tools VigiFlow and VigiLyze.

UMC gave workshops on VigiFlow and VigiLyze at COFEPRIS, Mexico's national pharmacovigilance centre

An additional e-learning course, **Introduction to Pharmacovigilance**, was released in both English and Spanish. The new module covers basic concepts as well as the history, need, aims and scope of pharmacovigilance. By June 2020, 8,500 learners had started the course in English, and 2,300 in Spanish, an encouraging response.

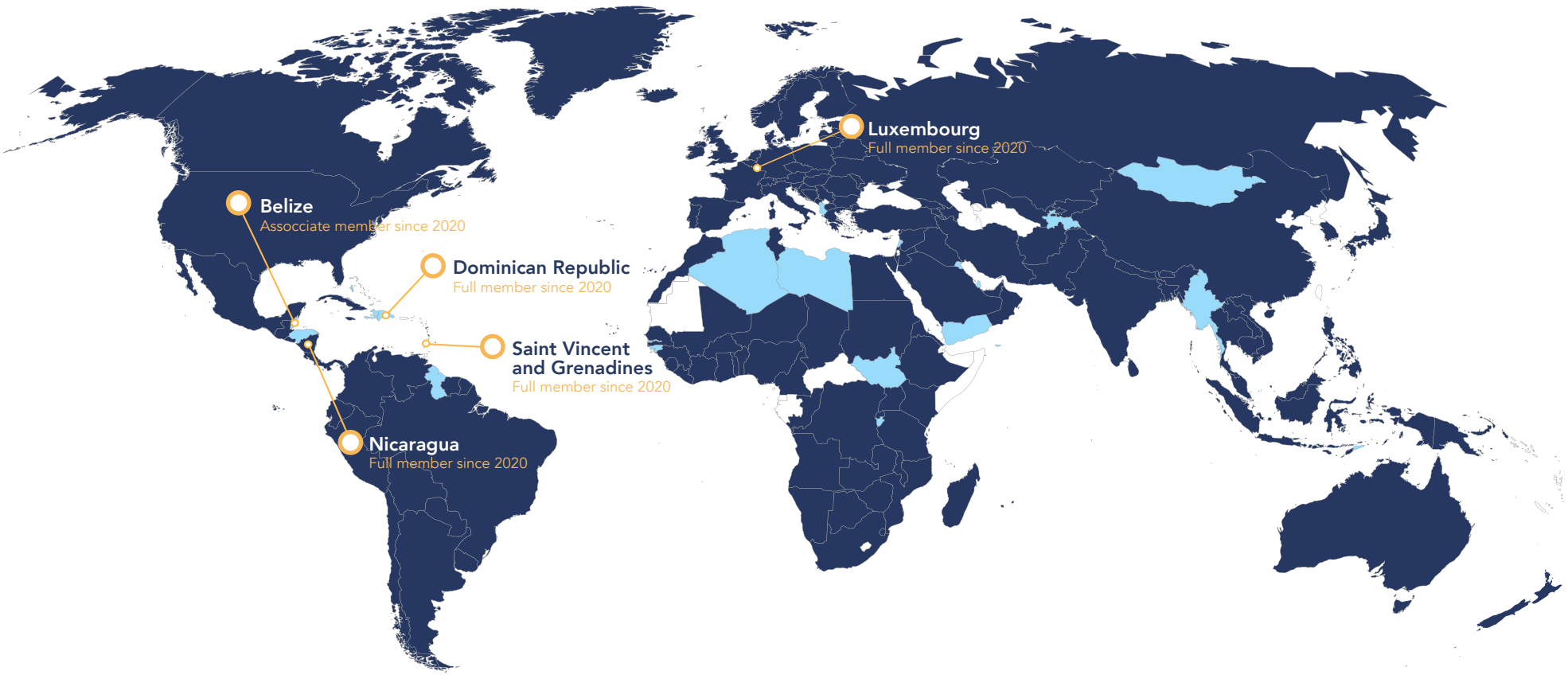
UMC co-organised two International School of Pharmacology Giampaolo Velo workshops – Understanding causal complexity: "**How individual patient experiences can enhance the quality and safety of healthcare**" (with the Norwegian University of Life Sciences, Oslo) and "**Improving the detection, analysis, and reporting of harms in medicines and devices**" (with the Centre for Evidence Based Medicine, University of Oxford).

Participants at The 4Es Forum in Erice, Italy, developed a set of 10 recommendations to improve detection, analysis, and reporting of harms from medicines and devices to improve patient safety

WHODrug User Group meetings took place in October 2019 (in Pennington, New Jersey, USA), and February 2020 (New Delhi, India). Webcasts replacing live presentations were held in spring 2020 alongside 13 WHODrug webinars, on topics such as new functionality, Standardised Drug Groupings, WHODrug Koda, WHODrug Global Chinese, and coding challenges.

A steady output of filmed and animated video content was produced to support UMC's events and products, and to raise awareness of pharmacovigilance initiatives. The mini-documentary "**Signal detection in Latin America**" was shown at the annual meetings for national centres and ISoP in Bogotá, Colombia in autumn 2019.

Members of the WHO Programme for International Drug Monitoring



UMC and COVID-19

WHO declared COVID-19 a public health emergency of international concern on 30 January 2020, and a pandemic on 11 March 2020. This naturally changed some of the plans that UMC had been working towards.

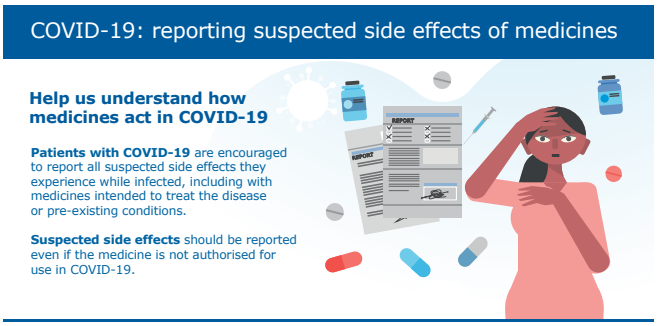
From March 2020 some UMC resources were quickly diverted to efforts to monitor medicines used for patients diagnosed with COVID-19. UMC compiled a list, updated on a weekly basis, of all newly **added COVID-related medicinal products in WHODrug Global** since the March 2020 release of the dictionary.

A new **section was created on UMC's website** where key information on UMC's COVID-19 activities was collected, with publicly available resources, as well as reference to user-only resources such as VigiLyze. UMC encouraged national centres to report all individual case safety reports (ICSRs) related to COVID-19 treatments and submit them frequently. The practice of reporting early rather than waiting for more information was promoted, as ICSRs can always be updated after submission. A newsletter was launched for members of the WHO Programme for International Drug Monitoring to address the increased need for information-sharing during the pandemic. UMC circulated two newsletters: one focusing on guidelines for analysis in VigiLyze, along with reporting guidelines on how to label and code ICSRs to support analysis; the second was intended to boost reporting among member countries in the programme. MedDRA released an updated version of its terminology, where terms related to COVID-19 had been added, and UMC updated its systems accordingly.

UMC also shared a **descriptive analysis of data in VigiBase on chloroquine and hydroxychloroquine**, due to patients self-medicating with chloroquine or hydroxychloroquine and causing themselves serious harm. This review was published in the **WHO Pharmaceuticals Newsletter as well as in VigiLyze**.

UMC Research resources were assigned to several related studies. In April 2020 regular analysis of global reporting of adverse drug reactions (ADRs) for medicines used to treat COVID-19 was established. By June 2020, seven reviews based on the 3,000 ICSRs reported in VigiBase had been shared via VigiLyze and made available to regulators in the weekly and then fortnightly WHO regulatory update. These were mainly descriptive and included reviews for all drugs in the WHO Solidarity Trial, alongside any other drug with at least 100 reports where COVID-19 was the indication for treatment. Reports were submitted by five of the six WHO regions, with the highest number coming from the WHO European Region. Publications related to COVID-19 included a **commentary on optimising safety surveillance for COVID-19 vaccines**, in Nature Reviews; **a commentary on the role of pharmacovigilance and the International Society of Pharmacovigilance during the pandemic**, in Drug Safety; and a manuscript that assesses gender differences in the reporting of suspected ADRs for COVID-19 treatments.

The UMC communications team liaised with the **European Medicines Agency (EMA)** to adapt a graphic communications campaign package that the EMA had created and made it available to the WHO programme. The package consisted of an infographic poster and social media card for healthcare professionals and patients, encouraging the reporting of ADRs to COVID-19 treatments. The materials were provided in an easily editable format, so national centres could create their own translations and add their logo and contact information.



Communications campaign package created by EMA and made available to the WHO programme

UMC publications

Gattepaille L.
Using the WHO database of spontaneous reports to build joint vector representations of drugs and adverse drug reactions, a promising avenue for pharmacovigilance. 2019 IEEE International Conference on Healthcare Informatics (ICHI), Xi'an, China, 2019, pp. 1-6, doi: 10.1109/ICHI.2019.8904551.

van Stekelenborg J, Ellenius J, Maskell S, Bergvall T, Caster O et al
Recommendations for the Use of Social Media in Pharmacovigilance: Lessons from IMI WEB-RADR. Drug Safety, Vol. 42, 1393–1407(2019)
Date: 2019-08-24

Rocca E, Copeland S, Edwards IR
Pharmacovigilance as Scientific Discovery: An Argument for Trans-Disciplinarity. Drug Safety, Vol. 42, 1115–1124 (2019)
Date: 2019-10-01

Watson S, Caster O, Rochon PA, den Ruijter H
Reported adverse drug reactions in women and men: Aggregated evidence from globally collected individual case reports during half a century. EClinicalMedicine. 2019 Oct 25;17:100188
Date: 2019-10-25

Wakao R, Taavola H, Sandberg L, Iwasa E, Soejima S, Chandler RE, Norén GN
Data-Driven Identification of Adverse Event Reporting Patterns for Japan in VigiBase, the WHO Global Database of Individual Case Safety Reports. Drug Safety, Vol. 42, 1487–1498 (2019)
Date: 2019-12-02

Dietrich J, Gattepaille L, Anne Grum B, Jiri L, Lerch M, Sartori D, Wisniewski A
Adverse Events in Twitter - Development of a Benchmark Reference Dataset: Results from IMI WEB-RADR. Drug Safety (2020) 43:467–478.
Date: 2020-01-29

Caster O, Aoki Y, Gattepaille L, Grundmark B
Disproportionality Analysis for Pharmacovigilance Signal Detection in Small Databases or Subsets: Recommendations for Limiting False-Positive Associations. Drug Safety (2020) 43:479–487.
Date: 2020-02-01

de Leon J, J. Sanz E, Norén GN, De las Cuevas C
Pneumonia may be more frequent and have more fatal outcomes with clozapine than with other second generation antipsychotics. World Psychiatry. 2020 Feb; 19(1): 120–121. Published online 2020 Jan 10. doi: 10.1002/wps.20707
Date: 2020-02-03

Lagerlund O, Strese S, Fladvad M, Lindquist M
WHODrug: A Global, Validated and Updated Dictionary for Medicinal Information. Ther Innov Regul Sci. 2020 Feb 20. doi: 10.1007/s43441-020-00130-6
Date: 2020-02-20

Chandler RE, McCarthy D, Delumeau JC, Harrison-Woolrych M
The Role of Pharmacovigilance and ISoP During the Global COVID-19 Pandemic. Drug Safety. 2020 Jun;43(6):511-512. doi: 10.1007/s40264-020-00941-4
Date: 2020-05-07

Chandler RE
Optimizing safety surveillance for COVID-19 vaccines. Nat Rev Immunol. 2020 Jun 17:1–2. doi: 10.1038/s41577-020-0372-8.
Date: 2020-06-17

Sandberg L, Taavola H, Aoki Y, Chandler R, Norén GN.
Risk Factor Considerations in Statistical Signal Detection: Using Subgroup Disproportionality to Uncover Risk Groups for Adverse Drug Reactions in VigiBase. Drug Safety. 2020 Jun 20. doi: 10.1007/s40264-020-00957-w.
Date: 2020-06-20

Härmark L, Weits G, Meijer R, Santoro F, Norén GN, van Hunsel F.
Communicating Adverse Drug Reaction Insights Through Patient Organizations: Experiences from a Pilot Study in the Netherlands. Drug Safety. 2020 May 16. doi: 10.1007/s40264-020-00932-5.
Date: 2020-06-25

Furlan G, Caduff-Janosa P, Sottosanti L, Cappello E, Valdiserra G, Tuccori M.
Drug Safety in Geriatric Patients: Current Status and Proposed Way Forward. Drug Safety. 2020 Jun 4. doi: 10.1007/s40264-020-00949-w
Date: 2020-06-25

Gattepaille LM, Hedfors Vidlin S, Bergvall T, Pierce CE, Ellenius J
Prospective Evaluation of Adverse Event Recognition Systems in Twitter: Results from the Web-RADR Project
Drug Safety. 2020 May 14. doi: 10.1007/s40264-020-00942-3
Date: 2020-06-25

Chandler RE
Nintedanib and ischemic colitis: Signal assessment with the integrated use of two types of real-world evidence, spontaneous reports of suspected adverse drug reactions, and observational data from large health-care databases. Pharmacoepidemiol Drug Saf. 2020 May 12. doi: 10.1002/pds.5022
Date: 2020-06-25

Hult S, Sartori D, Bergvall T, Hedfors Vidlin S, Grundmark B, Ellenius J, Norén GN
A Feasibility Study of Drug–Drug Interaction Signal Detection in Regular Pharmacovigilance. Drug Safety, Vol. 43, 775–785 (2020).
Date: 2020-07-17