

The year in review

July 2020–June 2021

Highlights of the year



UMC applied its newest methodological innovation, *vigiGroup*, which uses co-reporting patterns of reactions on ICSRs to group together ICSRs depicting a similar clinical picture



UMC expanded *VigiFlow* to support reporting and analysis of adverse reactions following immunisation for immunisation programmes (at district, provincial, and national level)



Agencies from Honduras and Albania (2020), Lebanon, Algeria, Kuwait, Libya, Gambia and Congo (2021) joined the WHO Programme for International Drug Monitoring



Five online courses, in English and Spanish, based on the micro-learning pedagogical approach evaluation published in *Drug Safety*



COVID-19 vaccines monitoring led to three signals as of June 2021 with additional signals under review



UMC's podcast *Drug Safety Matters* reached 13 episodes



Four MSc theses were successfully defended and published



Uppsala Reports published online before the content is gathered in print issues; 33 news articles appeared



Thirteen papers involving UMC authors were published in peer-reviewed journals



#MedSafetyWeek organised by UMC for the fourth time in November 2020, with a record 76 regulatory agencies



Updates to drug coding engine WHODrug Koda included use of country information to solve non-unique cases, improvements to identification of ingredient information, and the possibility to generate statistics



Online WHODrug User Group meetings throughout the year



UMC was involved in initiatives related to implementation of the ISO standards for Identification of Medicinal Products (IDMP)



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

Pharmacovigilance resources

UMC provides resources for pharmacovigilance practice via access to information as well as tools and services for members of the WHO PIDM 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.

VigiBase

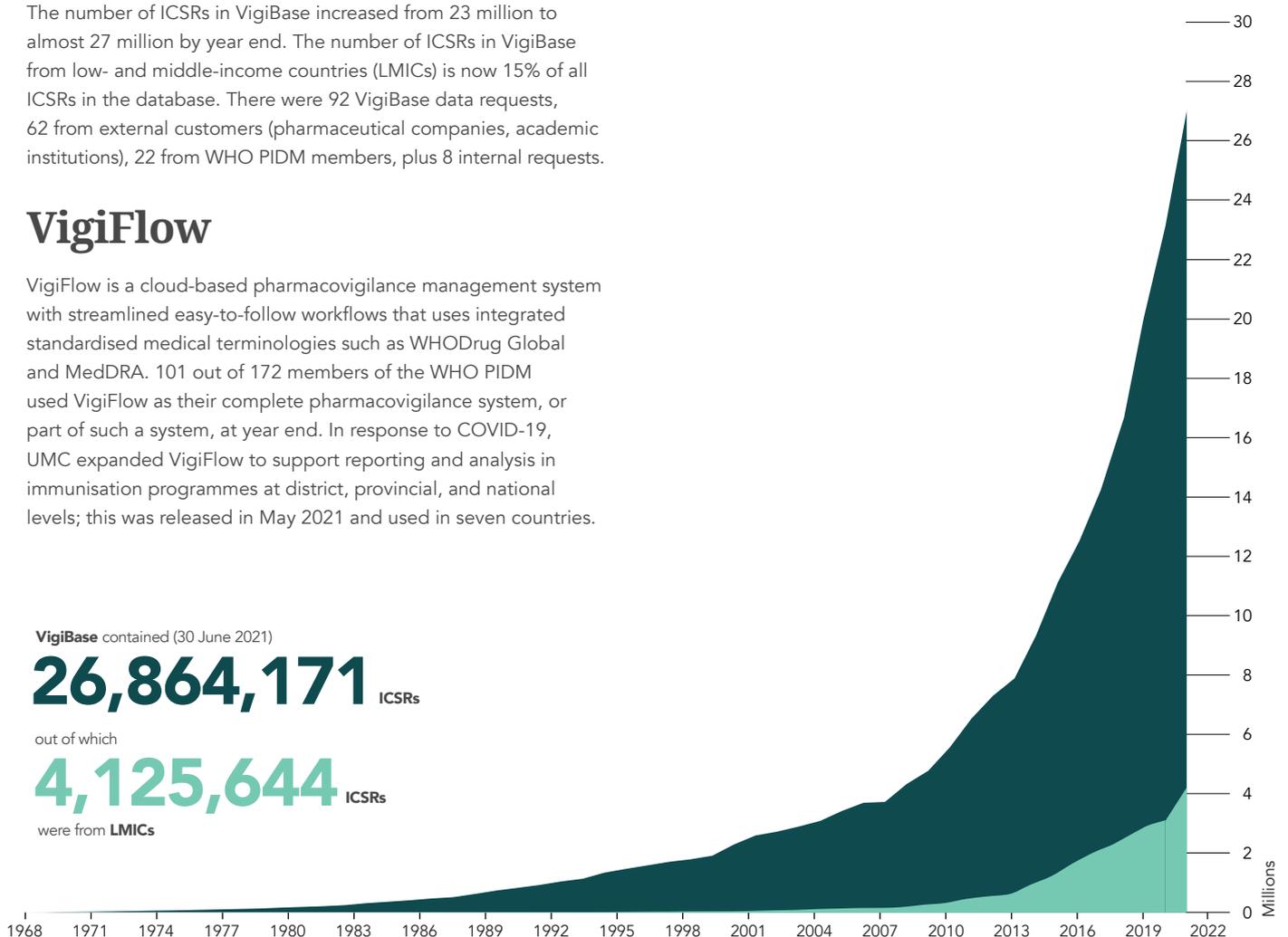
VigiBase is the unique WHO global database of reported potential side effects of medicinal products and is continuously updated. Alongside its data management and quality assurance tools, the VigiBase system is linked to standard international medical and drug classifications. These classifications enable structured data entry, retrieval and analysis at different levels of precision and aggregation, vital in effective and accurate analysis. Member countries of the WHO Programme for International Drug Monitoring (WHO PIDM) have been submitting reports since 1968. The number of ICSRs in VigiBase increased from 23 million to almost 27 million by year end. The number of ICSRs in VigiBase from low- and middle-income countries (LMICs) is now 15% of all ICSRs in the database. There were 92 VigiBase data requests, 62 from external customers (pharmaceutical companies, academic institutions), 22 from WHO PIDM members, plus 8 internal requests.

VigiFlow

VigiFlow is a cloud-based pharmacovigilance management system with streamlined easy-to-follow workflows that uses integrated standardised medical terminologies such as WHODrug Global and MedDRA. 101 out of 172 members of the WHO PIDM used VigiFlow as their complete pharmacovigilance system, or part of such a system, at year end. In response to COVID-19, UMC expanded VigiFlow to support reporting and analysis in immunisation programmes at district, provincial, and national levels; this was released in May 2021 and used in seven countries.

VigiLyze

VigiLyze is a signal detection and signal management tool that uses insights into the safer use of medicines from members of the WHO PIDM as a starting point for efficient quantitative signal detection. It supports national signal management processes, including qualitative assessments. VigiLyze gained more advanced statistical signal analytical capacity, vaccine by vaccine, as well as analysis across different vaccine platforms; data are updated in VigiLyze twice a week.



WHODrug Global and COVID-19

UMC continually monitors the COVID-19 situation. In that context, our current operations and initiatives include the following:

- All UMC's WHODrug-related operations and services have continued during this period, without disruption.
- We added a WHODrug Standardised Drug Grouping (SDG) for COVID-19 – “Drugs and vaccines for COVID-19” – for the 2020 September release of WHODrug, further refined for the March 2021 release. We created a COVID-19 vaccine subgroup to accommodate detailed analysis of issues related to vaccine platforms. And we released a guidance on the structure and naming of COVID-19 vaccines in WHODrug and the WHODrug Standardised Drug Grouping (SDG).
- To support the anticipated need to carefully monitor the adverse event profile of COVID-19 drugs and vaccines, COVID-19 products and substances in WHODrug Global have been added on a continuous basis to WHODrug and made available on a daily basis in WHODrug Insight.

WHODrug Link Korea

WHODrug Link Korea is the latest addition to the WHODrug portfolio, created to facilitate E2B(R3) ICSR reporting for the Republic of Korea using local Korean code identifiers. WHODrug Link Korea converts codes from WHODrug Global to local Korean codes, making the regulatory submission process easier and more efficient for WHODrug users. WHODrug Link Korea supports users of both the B3 and the C3 formats and was released for the first time on 1 March 2021. WHODrug Link Korea will be made available twice per year, alongside the release of WHODrug Global. From June 2021, WHODrug Link Korea was also included in WHODrug Insight.

Access Manager

A new WHODrug self-service function was launched in January 2021 and made available to all companies with a WHODrug Global licence. Appointed persons (referred to as Access Managers) can manage their WHODrug accounts themselves, resulting in quicker WHODrug access.

Access Manager makes it possible to get a detailed WHODrug Global licence overview; create new WHODrug accounts; search, edit, or delete existing accounts; and prepare for the pending addition of new WHODrug users.

Academic licence

During the year, UMC strengthened our offering for academic institutions by providing a wider range of WHODrug licences targeted towards that sector. This enables researchers to use WHODrug in situations where it was not previously an option, thus making sure that more groups get to benefit from UMC's work.

WHODrug Koda

WHODrug Koda supports the drug coding process by effectively providing both drug name coding and ATC selection. For March 2021, a number of updates to WHODrug Koda were released:

- Country information can now be used in Koda to solve non-unique cases.
- We improved the coding rules by implementing better identification of ingredient information.
- We added the possibility to generate a statistics report in Koda. This report shows information such as how many drug names have been coded with higher or lower certainty, and Koda intelligence versus direct hits.

WHODrug Global Chinese in CAT

The Chinese version of WHODrug Global has been a much-appreciated addition to WHODrug Global and, based on user requests, we updated the WHODrug Change Analysis Tool (CAT) for WHODrug Global Chinese. CAT allows the upload of proprietary data – for example, a synonym list – and full change analysis between two different versions of WHODrug Global Chinese. The user can review all deleted and updated records to get an in-depth understanding of WHODrug Global Chinese changes and prepare for updating the version. It is also possible to export a file with all deleted records in WHODrug Global Chinese and the new replacement record.

WHODrug User Group meetings

Due to the pandemic, all face-to-face User Group meetings over the period were replaced with virtual events and webcasts.

2020 Q3–Q4

- Japan, 10 December

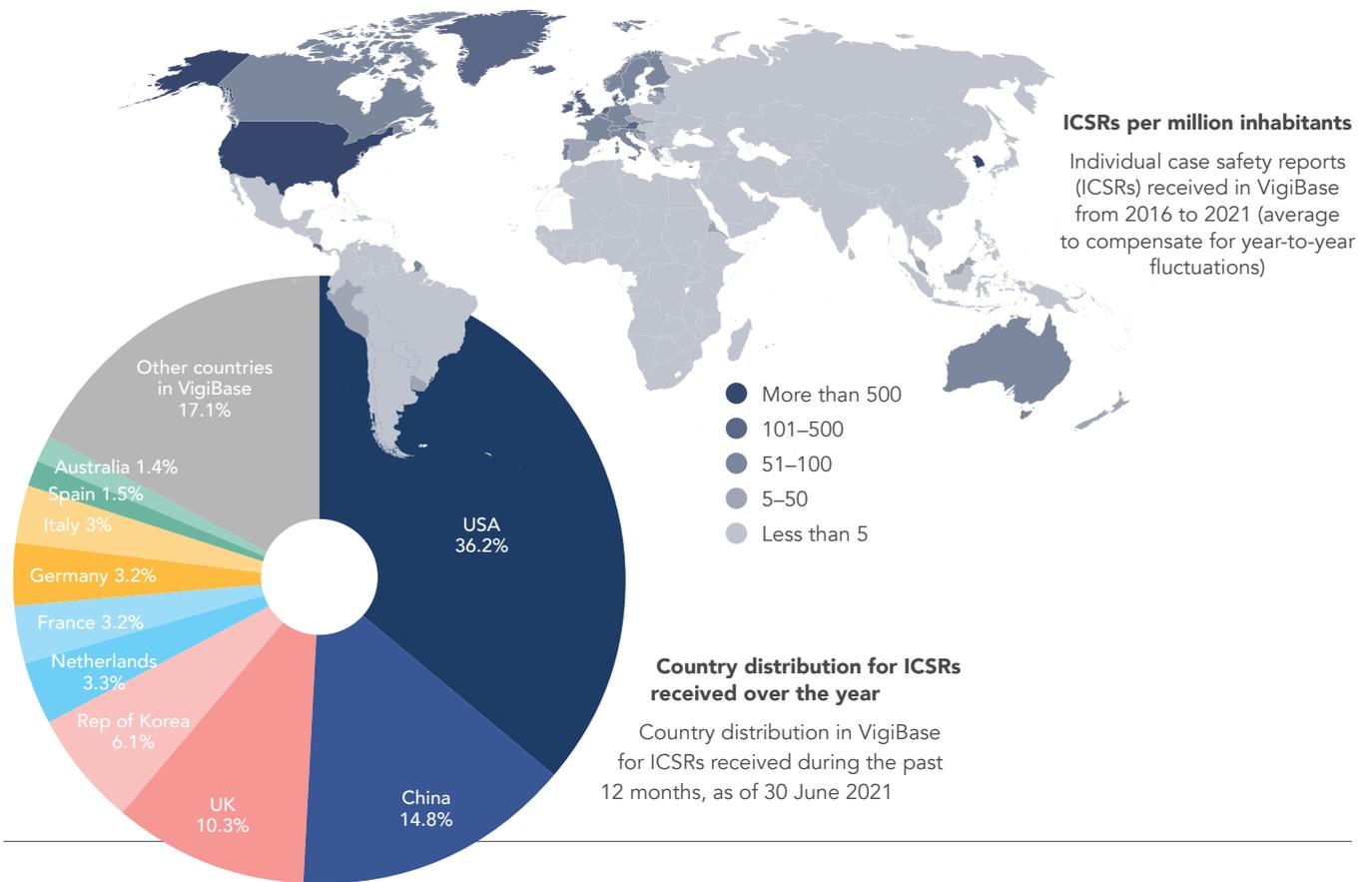
2021 Q1–Q2

- India, 4 March
- Europe, 15 April
- China, 18 May
- USA, 22 June

Webinars 2020–2021

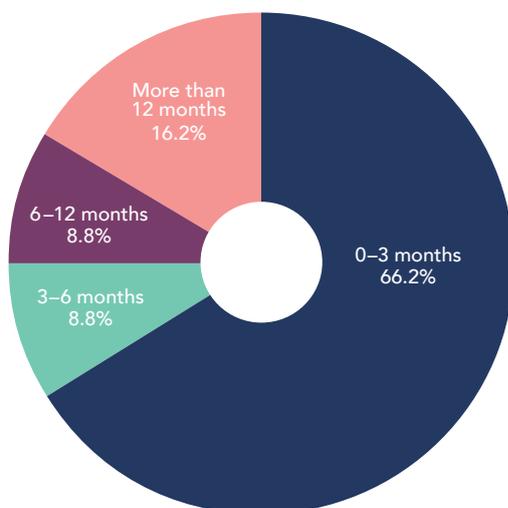
In the past year, we offered to registered users 11 webinars on various topics, such as new functionality in WHODrug, SDGs, Access Manager, WHODrug Link Korea, and coding challenges.

Quantity of ICSR reporting



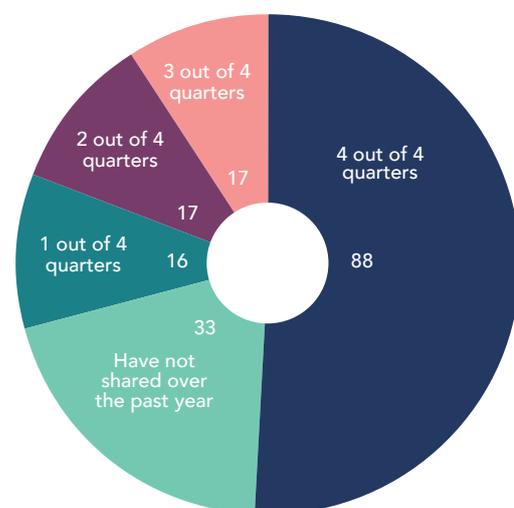
Frequency of ICSR reporting

Frequent submissions of new ICSRs are critical to detect signals and take appropriate action at an early stage. Member countries are expected to submit ICSRs to UMC on a regular basis; preferably **more than once a month**, but **at least every quarter**.



Time since last submission

Countries distributed according to time elapsed since last submission of ICSRs to VigiBase as of 30 June 2021. 66.2% of the member countries shared ICSRs with the WHO PIDM in the last quarter.



Number of countries submitting ICSRs in VigiBase, by quarter

88 countries have shared data in VigiBase all four quarters during the period 1 July 2020 to 30 June 2021.

Pharmacovigilance science and data science

A busy year for signals, publication of UMC signal detection methodology, and further research on de-identification, as well as safety monitoring of COVID vaccines.

UMC has been conducting scientific research for decades and strives to remain at the forefront of pharmacovigilance science development. In the Pharmacovigilance Science and Data Science sections, our core activities involve monitoring the safety of medicines globally and developing novel machine learning and statistical methods for pharmacovigilance. We do this by synthesising medical, pharmaceutical, and analytical expertise. In our research, we also collaborate with other institutions. This past year, although we had set ourselves a number of strategic goals at the start of 2020, the COVID-19 pandemic forced a pivot and we refocused most of our research efforts into the following two priorities:

1. Monitor the safety of COVID-19 treatments
2. Prepare for and perform safety monitoring of COVID-19 vaccines

Additionally, we have managed to keep ongoing activities on the two following strategic goals:

1. Safeguard and promote the clinical value and relevance of information in VigiBase
2. Provide high quality product portfolios to support life-cycle safety management

Finally, as part of our regular non-research activities, we have also supported VigiBase search services, providing high quality VigiBase data extractions and analyses for national pharmacovigilance centres worldwide, pharmaceutical industry entities, and academic institutions.

Activities and achievements

Monitor the safety of COVID-19 treatments

This priority guided the great majority of our activities during the second half of 2020. We produced regular reports providing overall descriptive statistics of reports in VigiBase for which COVID-19 could be suspected based on a number E2B fields (for example, reported indications or narrative), accompanied by a more in-depth clinical analysis of the picture they depicted. At the time of writing, we have produced 15 such reports and shared them with WHO and VigiLyze users, as the automatic verification of COVID-19 case reports cannot be done directly through VigiLyze. We have received very positive feedback from WHO about this regular report and, as of June 2021, the report had been downloaded around 2800 times. Throughout 2020, in parallel with the production of the COVID-19 cases descriptive

report, we monitored the WHO Solidarity Trial drugs as well as other real-world use of treatments for COVID-19. We have explored some aspects of these issues in greater depth, such as gender differences in the ADR profiles for the COVID-19 trial drugs (see publication reference on page 7), or specific drugs such as chloroquine and remdesivir.

Prepare for and perform safety monitoring of COVID-19 vaccines

This priority has been at the centre of our activities in the first half of 2021. Since the start of January, the number of COVID-19 vaccine ICSRs has been growing rapidly, reaching around 1 million by the start of June 2021, making COVID-19 vaccine the most reported active ingredient in the entire VigiBase (representing about 4% of all VigiBase reports). Given this volume of data, we also have collaborated with the VigiLyze development team to advise on the changes necessary to support better analysis of COVID-19 vaccine ICSRs.

For the benefit of national pharmacovigilance centres and WHO, we have produced a regular descriptive report, providing a panel of statistics on the COVID-19 vaccine ICSRs in VigiBase. By the beginning of June 2021, we had produced five of these reports and made them available in VigiLyze, generating around 1300 downloads.

Additionally, we have been continuously monitoring the COVID-19 vaccines ICSRs for their safety, by means of disproportionality analysis, as well as by following specific adverse drug reactions such as adverse events of special interest (AESIs) – a set of reactions defined by the Brighton Collaboration, which we adapted as algorithmic rules to conform with ICSR structure. During this monitoring, one of our key strategies has been to complement the work done by other pharmacovigilance organisations and focus on aspects where UMC has a unique opportunity to make an impact. To that end, we have been using one of UMC's newest methodological innovations, *vigiGroup*, a method which uses co-reporting patterns of reactions on ICSRs to group together ICSRs depicting a similar clinical picture. This method allows pharmacovigilance assessors to quickly get an overview of the different kinds of reaction profiles found for a given drug. Albeit still under improvement, the method has already helped our pharmacovigilance experts gather insights about the COVID-19 vaccines, leading to assessment of several potential safety signals, culminating in two safety signals shared in VigiLyze. Overall, by early June 2021, our COVID-19 vaccines monitoring activities had led to three signals, and a number of additional potential signals still under review.

Safeguard and promote the clinical value and relevance of information in VigiBase

We have continued the work on our project to automatically de-identify clinical narratives and have initiated a collaboration with the United Kingdom's national centre of pharmacovigilance, the Medicines and Healthcare products Regulatory Agency (MHRA). MHRA shared around 120,000 unredacted narratives received from UK's Yellow Card system MHRA shared with UMC around 120,000 unredacted narratives received from UK's Yellow Card system. We annotated about 60,000 narratives for personal identifiers, focusing on names, and will be using these annotations during the second half of 2021 to fine-tune our existing de-identification algorithm and hopefully obtain performance on par with human redaction.

This project is of great value for the future of VigiBase. Increasing the number of narratives in VigiBase increases the clinical relevance of this source of safety data. Our hope is that a performant algorithm could automatically de-identify narratives made available in VigiBase, which would support national pharmacovigilance centres in their need for addressing privacy regulations, while fostering the sharing of narratives across the member countries of the WHO PIDM.

Provide high quality product portfolios to support life-cycle safety management

We collaborated with individuals from the development team and from the WHODrug team to evaluate our drug coding engine, Koda, in the task of automatically coding drugs on ICSRs. Koda was originally designed to code concomitant medications in clinical trials, relying on artificial intelligence to map free-text verbatims containing medicinal products to the appropriate entries in WHODrug Global with great precision and consistency. In particular, it can capitalise on route, indication, and country information to resolve ambiguous tradenames. However, we believe evaluating the performance of Koda in the context of ICSRs will give insights on the potential of the coding engine for safety data and potentially demonstrate value for this additional market.

During 2020 and 2021, we have also continued the development of an automated pipeline for data mining of adverse events in DailyMed, the FDA resource of structured product labels. Although the algorithm extracting the data and mapping the adverse events found to MedDRA is still in need of further refinement to increase performance, the infrastructure to run the algorithm and store the data for use in different applications has been put into place. In the future, this project will produce a large knowledge base of quality labelled information and should facilitate signal detection activities. This resource could be of great value to VigiLyze and VigiFlow customers in the future.

Search services

Between 1 July 2020 and 31 May 2021, we delivered 92 VigiBase data requests: 62 from external customers (such as pharmaceutical companies and academic institutions), 22 from WHO PIDM affiliates, and eight from the WHO PIDM.

Research in numbers

- 10 publications with staff from our two sections:
 - Interstitial lung disease as an adverse drug reaction in Japan: Exploration of regulatory actions as a basis for high reporting (collaboration with the PMDA)
 - A feasibility study of drug–drug interaction signal detection in regular pharmacovigilance
 - Signals of adverse drug reactions communicated by pharmacovigilance stakeholders: protocol for a scoping review of the global literature
 - Sex differences in reported adverse drug reactions to COVID-19 drugs in a global database of individual case safety reports
 - Tumor necrosis factor inhibitor-induced pleuropericarditis: A retrospective evaluation using data from VigiBase
 - How far can we go with just out-of-the-box BERT models?
 - The use of subgroup disproportionality analyses to explore the sensitivity of a global database of individual case safety reports to known pharmacogenomic risk variants common in Japan (collaboration with PMDA)
 - Vaccination against COVID-19: insight from arterial and venous thrombosis occurrence using data from VigiBase (collaboration with the French Regional Centre of Pharmacovigilance in Paris)
 - Characterization of VigiBase reports on tinnitus associated with bisoprolol — An exploratory and descriptive study
 - The International Society of Pharmacovigilance (ISoP) Pharmacogenomic Special Interest Group: Pharmacogenomics in pharmacovigilance
- 12 signals made available in VigiLyze
- Two MSc. theses successfully defended and published:
 - Improving the speed and quality of an adverse event cluster analysis with stepwise expectation maximization and community detection
 - Extracting adverse drug reactions from product labels using deep learning and natural language processing
- Collaborations with the Dutch, Japanese, Moroccan, and British national pharmacovigilance centres, as well as the French regional pharmacovigilance centre in Paris
- Multiple presentations and seminars

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.

UMC's communications department continuously creates and delivers original content across multiple media platforms, producing ad-hoc campaigns and materials to promote emerging UMC initiatives and assist other departments with their communication needs.

Uppsala Reports magazine, the *Drug Safety Matters* podcast and UMC's social media channels have all increased their following and improved the quality of their output.

During the COVID-19 crisis, the team have used their skills and knowledge to great effect in supporting UMC's pandemic response both internally and externally to make sure that crucial information has reached its intended audience in good time.

Activities

Uppsala Reports magazine has followed a web-first strategy since spring 2020, whereby articles are published on UppsalaReports.org first and published in print form later. Over the year, 33 news articles were published online and two print issues of the magazine were mailed to national pharmacovigilance centres.

Web and social media

UMC's social media channels are growing steadily and have gained more than 47,000 followers across LinkedIn, Facebook, Twitter and YouTube – an increase of 34% from the previous year.

Relevant content and regular updates to UMC's website who-umc.org has ensured a 15% year-on-year increase in website traffic, with the most visited pages relating to WHODrug, UMC's educational offering, and VigiBase. Notably, visits to pages related to VigiBase increased by 60% compared to the previous year.

UMC coordinated the annual social media campaign #MedSafetyWeek for the fourth time in November 2020. UMC invited the entire WHO PIDM network to participate, and a record 76 national regulatory agencies joined in. An additional 10 supporting organisations, including WHO, also took part in the campaign. Participants shared three animations, translated into their local language and with their logo, across Twitter, LinkedIn, Facebook, Instagram, and YouTube, reaching a total of 141.9 million people. The animations were translated into 45 languages.

Video and podcasts

A steady output of filmed and animated video content was produced over the year to support UMC's services, products, and research, and to showcase UMC as an attractive employer and important actor in our field. Notably, a short documentary titled

"Pharmacovigilance in a time of crisis" offered a look into the work of three UMC employees during the COVID-19 pandemic. A series of three animated videos was produced in collaboration with WHODrug and sales staff as part of a marketing campaign for the new coding engine WHODrug Koda.

UMC's podcast *Drug Safety Matters* (drugsafetymatterspod.org), launched in early 2020, provided a platform for in-depth interviews on subjects such as COVID-19 vaccine safety, intuition in pharmacovigilance, and antimicrobial resistance. The podcast has a main track with long-form discussions and a secondary track with audio versions of feature articles from *Uppsala Reports* magazine, plus short interviews with the article's author. A total of 13 episodes were published over the year.

Internal communications

The intranet is the cornerstone of UMC's digital work environment, keeping staff updated on recent events and new policies and providing easy access to important internal documents and processes. The top news feed saw more than 50 articles published, and the team news and announcement sections saw around 180 notices posted by staff members directly, testifying to the power of the intranet as an information-sharing and community-building platform in which staff members have an active voice.

Communications during COVID-19

Several original COVID-19-related stories were published in various formats, such as numerous articles in *Uppsala Reports* magazine, the short documentary "Pharmacovigilance in a time of crisis", and the podcast episode "Keeping vaccines safe". The latter two feature UMC staff members and their work.

The COVID-19 section on the UMC website was kept updated with key information related to UMC's COVID-19 activities and publicly available resources, as well as clear references to user-only resources such as VigiLyze.



Education and Training

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.

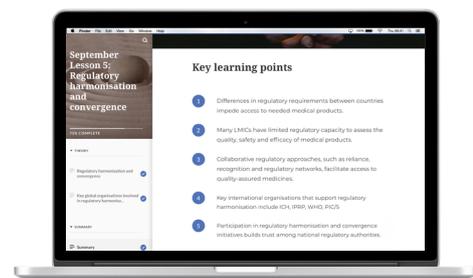
E-learning grew

A separate education and training strategy was developed for the first time in 2020. We envision a broader scope for our training and a closer alignment with WHO. At the heart of this strategy is our "theory of change" and a commitment to practising evidence-based educational development, both with regard to needs assessment and impact evaluation. This has transformed the way we work. Another principle is to shift our pedagogical approach towards remote learning. Furthermore, a business model for UMC courses has been developed to ensure their sustainability.

In 2019, UMC organised a signal detection workshop in Peru for pharmacovigilance officers from five Latin American countries (Argentina, Brazil, Chile, Ecuador and Peru) to demonstrate the usefulness of Vigilyze in signal management. The results of the impact evaluation showed that two signals identified during the course were later completed and shared in Vigilyze and that three countries started to adapt their signal SOPs to course guidelines, with Brazil and Argentina now looking to share all their reports in VigiBase. The continued need for advanced training in signal assessment to sustain improvements to national pharmacovigilance systems in Latin America and beyond has led to a new distance learning initiative called "distance tutoring" in which small groups working on data relevant to them are taught to work independently. We piloted our approach to distance tutoring with two assessors from Peru. An initial impact evaluation showed that it has the potential to significantly improve critical analytical skills. An evaluation of its impact on organisational behaviour will be carried out in August 2021, with a further evaluation on published safety communications due in January 2022.

UMC has offered e-learning now for many years. We currently offer five courses in signal detection, causality assessment and statistical reasoning, and one introductory course in pharmacovigilance. These courses are available in English and Spanish and take a micro-learning based approach to education, with training broken up into short modules to make it easier for learners to follow. In 2020, an evaluation of the first five courses was published in *Drug Safety* (1). The study revealed that the courses had learners from 137 countries, predominantly from within industry, national centres, and academia. The overall satisfaction rating was very high for all courses with over 90% of learners judging it to be either "excellent" or "good".

We also invested in a new learning management system (Matrix LMS) which will serve as a hub for all UMC's training activities. The platform hosts e-learning courses, instructor-led online courses,



provides opportunities for social interaction and social learning, quizzes, surveys, and more. It also has integrated marketing features and payment processing.

The international pharmacovigilance training course, which UMC has more or less held annually since 1993, was transformed into an instructor-led online course. The first course – offered in a limited format in the autumn of 2020 – was well received by learners and served as a useful primer in remote teaching methods. During the spring of 2021, the full international pharmacovigilance training course went online, and was also much appreciated by learners.

In 2020, UMC and the Consortium for Advanced Research Training in Africa (CARTA) pioneered a new approach to support pharmacovigilance research involving researchers from African universities and national centres. The lead investigator, Dr Henry Zakumumpa, of Makerere University, School of Public Health in Uganda, received funding for a two-year project – "Strengthening patient-centred pharmacovigilance in the health system in Uganda in the context of differentiated antiretroviral therapy delivery" – with researchers from the National Drug Authority in Kampala. After its first eight months the project was running smoothly and going to plan.

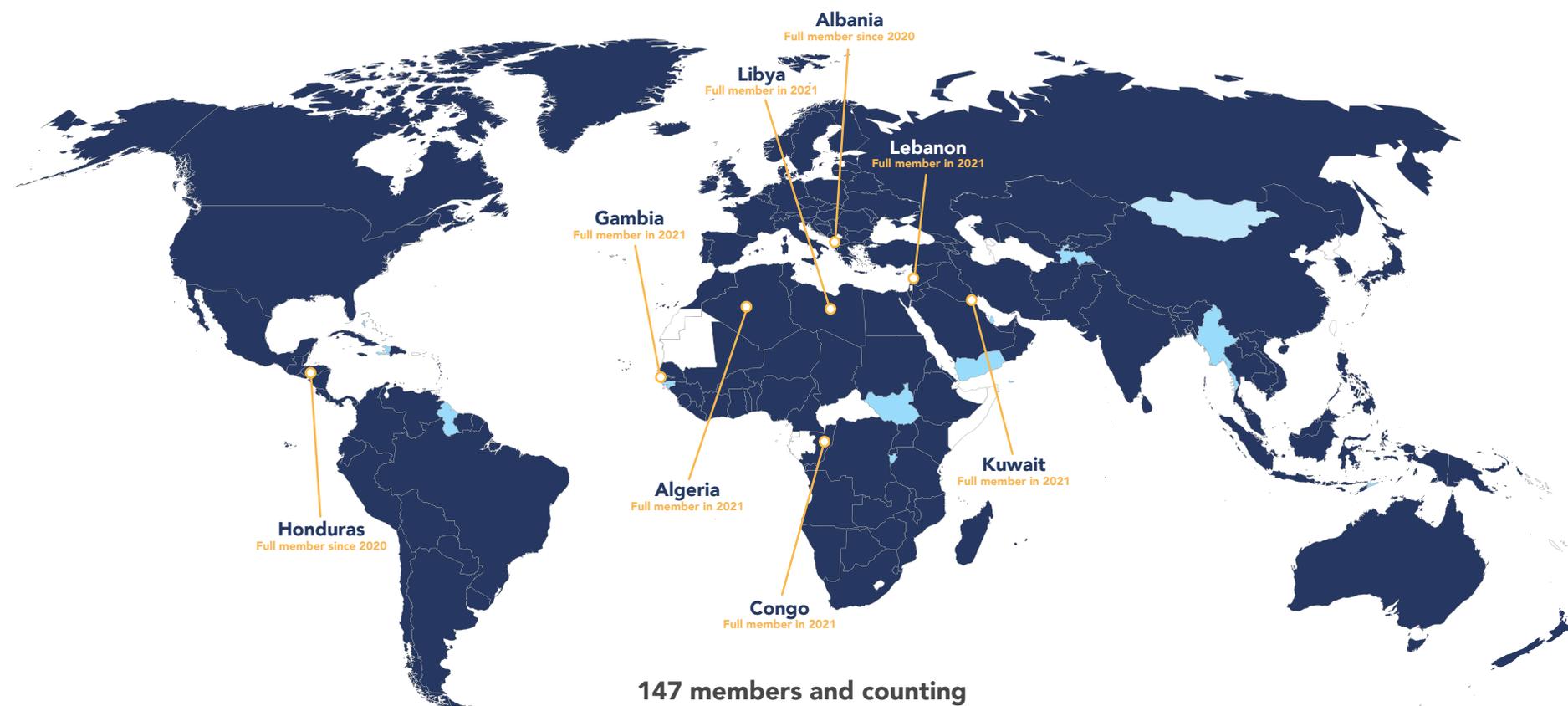
UMC took part in 16 online conferences and training events, reaching hundreds of pharmacovigilance professionals on all continents. This was done in collaboration with organisations such as the World Health Organization (WHO), Council for International Organizations of Medical Sciences (CIOMS), International Society of Pharmacovigilance (ISoP), Korea Institute of Drug Safety and Risk Management (KIDS), Council of Ministers of Health of Central America and the Dominican Republic (COMISCA). UMC's contributions varied from basic introductions to UMC to advanced signal analysis workshops.

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Members of the WHO Programme for International Drug Monitoring

● Full member
 ● Associate member
 ○ New member



Technical and operational support to member countries of the WHO PIDM is a core UMC activity, including guidance on becoming, and being, a member of the WHO PIDM. During 2020–2021 agencies from these countries joined: Honduras, Albania, Lebanon, Algeria, Kuwait, Libya, Gambia and Congo. Organisations joining the WHO PIDM receive an introduction to UMC pharmacovigilance tools. As of 30 June 2021, the WHO PIDM had 147 full members and 24 associate members.

Pharmacovigilance and COVID

WHO declared COVID-19 a public health emergency in January 2020, and a pandemic in March that year; this naturally changed some of the plans that UMC had been working on.



The World Health Organization declared the SARS-CoV-2 outbreak a Public Health Emergency of International Concern on 30 January 2020 and a pandemic on 11 March 2020. Vaccine development moved at unprecedented speed with the first vaccines made available in December 2020 by WHO and regulatory authorities in the US and Europe through emergency use authorisation or conditional marketing authorisation. UMC continued to develop new systems and features to provide members of the WHO Programme for International Drug Monitoring with training and support in AEFI recording, processing and analysis, sharing of data with WHO's global database, and signal detection.

The pandemic has made the work of the global pharmacovigilance community more important than ever. Alongside the efforts of the medical and scientific community to find suitable treatments and vaccines for COVID-19, the WHO PIDM has also been vital to the success of public health initiatives across the globe. Many might be directly affected by the virus, both on a professional and personal level, and challenges with rolling-out the new vaccines. This pandemic has locked down societies around the world. In particular, UMC has urged national pharmacovigilance centres to send in all ICSRs and AEFIs related to COVID-19 treatments and to submit those reports frequently to keep track of any potential safety concerns. The principle of reporting early rather than waiting for more information was adopted as ICSRs and AEFIs can be updated once they have been submitted if more information about an adverse event comes to light. Interactions and data sharing between national pharmacovigilance centres and immunisation programmes have also been encouraged through joint training sessions to show various stakeholders how UMC tools can support collaboration.

Other initiatives include:

- A dedicated COVID-19 section on UMC's website
- Regular descriptive analyses of VigiBase data
- Since early April 2020, UMC has used WHO's global database of reported potential side effects of medicinal products to make a descriptive analysis of adverse drug reactions related to COVID-19 treatments. The last of 15 such reports was issued in December 2020.
- Since January 2021, UMC has used VigiBase to make a descriptive analysis of the COVID-19 vaccine AEFIs submitted by members of the WHO PIDM. These reports are issued once a month through VigiLyze to all members. The vaccine reports are also shared with the subcommittee of the Global Advisory Committee on Vaccine Safety (GACVS) which meets regularly to discuss AEFIs of concern.

UMC has also been involved in working groups for the preparation of:

- COVID-19 vaccines: safety surveillance manual – WHO
- Performance evaluation framework for WHO-listed authorities
- GACVS COVID-19 Subcommittee
- Webinars for WHO Regional Offices – to showcase UMC's offerings to members of the WHO PIDM
- Workshops/webinars as a member of the advisory board of PAVIA.

Interstitial lung disease as an adverse drug reaction in Japan: Exploration of regulatory actions as a basis for high reporting

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