



# ANNUAL REPORT

July 2015 - June 2016



## **A LOOK BACK**

**Our vision** is a world where all patients and health professionals make wise therapeutic decisions in their use of medicines.

**Our mission** is to support and promote patient safety through effective global pharmacovigilance practice.



## **Foreword by the Director**

Another year has passed and we ask ourselves: have we made a full year's progress? Do our achievements match the time and resources we've spent on them? Like many of you reading this report, I suspect, I often feel that things move too slowly, that we struggle to keep up with ever-increasing demands.

You will make your own judgment as you read this report of our work last year. While we never get as far as fast as I wish, I do believe that you will see a record of solid progress and good work here at Uppsala Monitoring Centre (UMC). As ever, our goal to promote the safer use of medicines and help patients and clinicians making wise therapeutic decisions, has been at the heart of our work.

Everything we do has the safety and wellbeing of patients in mind. We understand just how complex treatments and the lives and behaviour of patients are, and that concentrating on individual drugs will no longer serve therapeutic effectiveness and patient safety; We are engaged in a field that embraces science, psychology, sociology, economics, communications – and much more. UMC is inevitably several stages removed from direct influence on clinicians and patients, but what we do and what the whole pharmacovigilance community does matters in the lives of everyone in every part of the world. We have to make sure that last year's work, this year's work, and next year's work really focus on that vital truth.

We are pleased with what we have achieved in the last year, but far from complacent there is still so much to do, and do better. But the most important evaluation of UMC and its hard-working team must be made by member countries of the World Health Organization (WHO) Programme for International Drug Monitoring (WHO PIDM) and those many others we serve. Are we delivering what you require and are we helping you pursue the goal of safer use of medicines throughout the world?

I hope you will be reassured by what you read in this Annual Report, but that you will also let us know if you feel there are ways in which we can be more effective and useful.

Best wishes,

Marie Lindquist Director, CEO

Marie Longs



### What's in this report?

We hope to give you a glimpse of the last 12 months' challenges and achievements, and a taste of the range and depth of UMC's work in pursuit of a safer use of medicine worldwide. We hope to engage your interest and support! On the last pages, there are statistics and further information that you may like to review.

## **Overview**

**UMC's commitment** to building a global safety culture is a daily preoccupation for staff, who focus on developing the science and practice of pharmacovigilance and making data and research useful.

Our primary areas of work are:

- support and development of pharmacovigilance with and for member countries of the WHO PIDM;
- education and training in pharmacovigilance at advanced and basic levels;
- innovative scientific research and method development in all areas of the identification, analysis, and prevention of harm to patients, including associated communication;
- production and development of the world-standard reference works in the WHODrug portfolio.

As well as collaboration with member countries of the WHO PIDM, we have partnerships with hundreds of individuals, institutions, professional societies, research units, government departments and commercial operations in all aspects of medicines safety. Our aim today, as it has been for nearly four decades, is to contribute to improvements in the lives and safety of patients around the world.

## Transforming research into action

**During the last 12 months**, the UMC has explored new scientific and methodological territory and the team as a whole has moved ahead in various areas, while maintaining and improving core systems and services. We have continued to work closely with the 124 member countries of the WHO PIDM, often on an individual basis.

As a WHO Collaborating Centre, UMC provides scientific leadership and operational support for the WHO PIDM and receives support and guidance from the WHO Advisory Committee and WHO-appointed UMC Board members. Through the WHO Safety and Vigilance team, UMC and WHO collaborate to build and strengthen global systems, facilitate exchange of information and learning, and develop capacity for effective surveillance of medicinal products. WHO and UMC have had a successful partnership for almost half a century with patient safety and wellbeing as the top priority.

## - Building a global safety culture

## Bringing knowledge to where it is needed

**Global pharmacovigilance has** continued to expand this year. At the time of publication there are 124 full and 29 associate member countries in the WHO PIDM. Membership includes countries with mature pharmacovigilance systems as well as those who are just starting out. All countries have different needs and challenges.

At the request of member countries, UMC offers support and guidance and provides tools in many areas:

- collection and management of medicines safety data;
- materials relating to international standards and terminologies for coding information, to facilitate the transfer and sharing of information globally;
- systems, such as VigiFlow, and best practice guidance for managing, storing, analysing, and sharing data;
- access to data in VigiBase via VigiLyze, an analytic tool to assist in answering complex medicines safety questions;
- communications training sessions, awareness campaigns, education materials and advocacy tools.

All UMC's work has the goal of helping transform data into useful knowledge and, ultimately, into wise choices in clinical practice. With VigiBase as the global database of safety information, the detection and dissemination of signals of suspected drug safety concerns is a major focus. Associations between harm to patients and suspected drugs, reported in Individual Case Safety Reports (ICSRs) from around the world, are constantly scanned and examined, linked and mapped in the search for those that have plausible causality and may require further investigative or regulatory action.

UMC's training and technical and scientific efforts also have the goal of supporting the establishment and development of robust, effective, patient-centred pharmacovigilance systems around the world.

The activities of UMC, the WHO Collaborating Centre for International Drug Monitoring, are based on an agreement dating from 1978, updated in December 2001, between the WHO and the Swedish government. The centre is managed by a director, appointed by a board of six members with personal deputies, three appointed by the Swedish government, three appointed by WHO.

UMC is an independent non-profit foundation and centre for international service and scientific research.

Our ambition is to enable wise therapeutic choices by transforming data into information and knowledge. We hope to help stakeholders identify issues of concern, find answers and drive change. Supporting others in their development and growth is central to our work.



More information can be found on the UMC website (www.who-umc.org) and direct enquiries are always welcome (info@who-umc.org).









# PUTTING PASSION INTO ACTION











## **Engaging a global community**

Over the last 12 months, UMC staff have taken part in support and training activities in a dozen countries, and have run or participated in pharmacovigilance training courses in Asia, Africa, South America, and Europe. This work included training in specialist areas such as signal detection, the use of UMC data management tools such as VigiFlow, vigiGrade, eReporting, VigiLyze and VigiAccess. A "Simplified E2B Guide for Primary Reporters" was published, aimed at vendors, systems developers, and others to provide understanding of the fundamentals of E2B.

Effective health communication skills, benefit-risk communication, and safety reporting processes are some of the topics that have been included in our training courses. Securing funds to maintain sustainable pharmacovigilance systems is a continuous challenge for many countries in the WHO PIDM. As pharmacovigilance evolves, expectations grow about showing the beneficial impact of activities, and it can be difficult to understand and meet the interests of the multiple stakeholders involved.

First steps to better support countries in this area have been taken in UMC's International Pharmacovigilance Training Course, adding sessions on sources of funding and pharmacoeconomics. The 2<sup>nd</sup> Asia Pacific Pharmacovigilance Training Course in Mysuru, India and the 18<sup>th</sup> International Pharmacovigilance Training Course in Uppsala, Sweden attracted over 40 participants representing 29 countries. Valuable relationships were created between participants, enabling a close exchange of experiences and ideas. UMC personnel have contributed to professional meetings and research conferences across the world. A WHO-UMC-HSA Inter-Regional Pharmacovigilance Training Course took place in Singapore in September 2015.

Webinars have been held in five languages, principally on VigiLyze, and individual technical support has been provided in response to hundreds of - often complex - enquiries and research requests. A range of guidelines, manuals, and support materials on various topics, as well as links to resources available elsewhere, have been provided.







<sup>&</sup>lt;sup>1.</sup> E2B is the global standard for the electronic transmission of ICSR data, established by the International Conference on the Harmonization of Technical requirements for Registration of Pharmaceuticals for Human Use (ICH)

## **Bringing change**

**UMC's impact on patient safety** can be seen in a number of ways, though few are readily quantifiable. The steady growth of membership in the WHO PIDM and the adoption of UMC's core tools, such as VigiFlow, are two indicators of our influence and usefulness. Attendance at UMC training events, in-house and in individual countries and for regional groups – and positive evaluations of them – confirm generally high levels of usersatisfaction.

UMC's voice and experience are valued by many audiences. UMC and the National Centre for Advancing Translational Sciences at the National Institutes of Health (NIH/NCATS) hosted a two-day meeting in Uppsala that addressed the scientific and information technology aspects of defining, registering and linking essential information related to substances in medicinal products.

At UMC's biennial research conference, Uppsala Forum, 18 experts addressed an international audience of 70 on the pharmacovigilance community's role in contributing to the safety of novel medicines when rapid access is of paramount importance. Other topics of discussion were medicines safety in resource-poor settings, drug repurposing, patient advocacy, emergency vaccine development, and pharmacovigilance impact assessment.

Take&Tell, the pharmacovigilance awareness campaign with a catchy song that encourages patients to tell their health professionals about adverse effects, attracted more interest over the year, and brochure versions in Arabic, French, Spanish, and Chinese were published. A Chinese version of the soul song was launched in China. This campaign is the first stage of UMC's growing efforts to enhance public pharmacovigilance communication. Take&Tell was constantly promoted in forums and courses during the year, and the campaign materials were used not only by national centres but also by patient organizations and the pharmaceutical industry. Feedback confirms the need to raise awareness and shows that Take&Tell can be useful in supporting this mission. With raised awareness,

the importance of safety monitoring of medicines reaches a wider audience, and increases the chances of influencing those responsible for legislation and the funding of pharmacovigilance activities.

Widening our sphere of influence, UMC's social media channels have continued to attract a steadily growing following. To date, we're active on LinkedIn, Facebook, Twitter, and YouTube. Our social media channels reach a wide and engaged audience of pharmacovigilance advocates, health professionals, patient groups, and the general public worldwide. We share news from the organisation and its collaboration partners; provide information about upcoming events; promote medicines safety awareness among professionals and the general public; and have laid the groundwork for several effective channels to meet future communication demands.

A regular presence online allows us to connect with our audiences directly. We encourage contact and typically respond to questions within 24 hours. Social media is an excellent way to reach new audiences who may have an interest in medicines safety or need to learn more about it, but lack access to other sources. Being accessible to these groups is a key objective of our social media presence.

Uppsala Reports celebrated 20 years of publication with a visual and editorial makeover in 2016. The content includes current affairs in pharmacovigilance and related fields, and news from UMC and member countries of the WHO PIDM. There is an in-house editorial committee that relies on contributions from members of the global pharmacovigilance community as well as UMC staff and other colleagues. Uppsala Reports is available free as a digital subscription, and is posted as a hard copy to the National Pharmacovigilance Centres of members of the WHO PIDM, who can circulate copies within their own networks.

Through this and other activities we hope to see the safer use of medicines as a topic for wide discussion - in hospitals and clinics as much as in schools and local communities.



## "Communication is about the stories you tell and the changes they bring."



Email us at info@who-umc.org to subscribe to the digital edition of Uppsala Reports, or to suggest an article submission.

## **Products and services**

Robust data management and analysis tools are critical to succeed in establishing a functional and healthy pharmacovigilance system. No number of Individual Case Safety Reports (ICSRs) can influence clinical practice and inform therapeutic decisions if there are not efficient and sensitive systems for managing, assessing, and analysing the data. No vision of global patient safety can be realized if there are not common, standardized methods for recording and sharing data.

Over the years, UMC has developed a suite of tools (software systems and programs) that provides individual countries with the means to manage and analyse their own data. At the same time, they can contribute to the overall data pool through regular submissions to VigiBase, either by using VigiFlow or by submission in other formats. An increasing number of countries are using UMC tools to simplify their own domestic systems and advance harmonisation and communication across the world.

UMC continues to offer a broad selection of products and services developed to enhance different aspects of medicine safety. 2015-2016 saw progress in the areas of:

- WHODrug portfolio with the launch of WHODrug Insight;
- differentiated signal sprints<sup>1</sup>;
- wider, refined use of vigiRank in signal detection;
- major improvements of VigiLyze, including an updated interface and added search functions.

Many companies and research organisations throughout the world use WHODrug as their primary coding source for medicinal products. This year, as always, the task of maintaining, updating, and refining the WHODrug portfolio continued. The year's releases of the suite of products and services (WHODrug Enhanced, Cross reference tool Japan, Cross reference ATC 5 and CAT) support WHODrug's role in optimizing the global coding, analysis, and reporting of medical product information during the whole life cycle of a drug. For example, Cross reference ATC 5 provides a mapping between the WHODrug code and the 5<sup>th</sup> level ATC - which is a targeted product for pharma companies submitting information on medicinal products to the European Medicines Agency (EMA).

WHODrug Insight, a new and improved online search tool for WHODrug, was released. WHODrug Insight offers a user-friendly interface and improved functionality to browse and analyse global content. The tool was purpose-built in collaboration between a committee of WHODrug users and UMC staff; it aims to increase efficiency, and improve review when coding and analysing medications in clinical trials and safety reports.

## Our Vigi portfolio of tools and services

- VigiBase: the WHO global ICSRs database.
   VigiBase includes data on conventional medicines, traditional medicines (herbals), as well as biological medicines, including vaccines.
- VigiLyze: a powerful search and analysis tool that provides WHO PIDM members access to more than 13 million ICSRs in VigiBase, submitted by over 100 countries.
- VigiAccess: giving public access to VigiBase through a user interface that allows search and retrival of statistical data on safety issues reported to the WHO PIDM.
- VigiFlow: a web-based ICSR management system designed for use by national centres in the WHO PIDM.
- VigiFlow eReporting: a web-based module for VigiFlow that allows national centres to capture ICSRs directly from patients and healthcare professionals.

## Our vigi 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.

<sup>&</sup>lt;sup>1.</sup> Sprint: Full-team presence in an accelerated, time-limited signal detection process



## Leading with innovative research

**UMC is continuously improving** its performance and seeking new and better ways of identifying and meeting patients' needs, characterising medicines safety issues to help regulators and health professionals recognize problems early, and protect patients from harm.

The research team both drives this ambition and responds to needs and challenges as they arise internally or from external requests and suggestions. The vaccine signal sprint, which highlighted 12 potential signals including a cluster of unexpected and rare skin reactions, marked a milestone towards UMC's long-standing aim to advance global vaccinovigilance.

To explore how methods developed by UMC for effective analysis of VigiBase can best be used to support signal detection in VigiBase from the perspective of a national centre, a signal detection workshop was held at the Indian Pharmacopoeia Commission (IPC) in Ghaziabad. It used an analytical approach developed with the Indian National Pharmacovigilance Centre, with the aims of identifying regional risk variation, improving the analytical capacity of WHO PIDM member countries, and demonstrating the relevance of UMC signal detection methods. The meeting was successful in finding a total of 20 drug-ADR combinations that were recommended for in-depth assessment.

In a separate exercise, an office-based signal sprint was undertaken to ensure sensitivity to safety signals relevant to Africa, Asia, and Latin America. This provided evidence of the relevance of our signal detection work to emerging countries within the WHO PIDM.

UMC's adverse event cluster analysis algorithm was fine-tuned, shortening run times. It was used to support the Danish National Centre's evaluation of HPV and POTS. This fine-tuning enables more sophisticated analysis of VigiBase and other observational medical data where we can find clusters of reports describing similar adverse events that use different terminology.

Recent scientific papers have suggested that an algorithm to detect unexpected time-to-onset might improve statistical signal detection in pharmacovigilance. In contrast, a UMC study found that when evaluated against emerging safety signals, the proposed algorithm performs worse than standard methods such as disproportionality analysis.

During the year, UMC continued its involvement in two collaborative research projects. The findings of the European IMI PROTECT (Pharmacoepidemiological Research on Outcomes of Therapeutics) project were published and covered:



- choice of measure and threshold for pair-wise disproportionality analysis;
- choice of measure for statistical interaction detection;
- subgroups versus stratification;
- duplicate detection;
- use of adverse event terminologies in statistical screening.

These significant findings involved evaluation of methods across many different data-sets. The PROTECT project was finished in February 2015.

The IMI WEB-RADR project, an important attempt to better understand patients' perspective through social media traffic, is on-going with significant progress in developing means to filter the mass of unrelated postings, thus greatly increasing the proportion of relevant hits in studies.

A significant number of UMC staff undertake visits to different centres each year, watching, listening and bringing home ideas and projects that underlie the future thinking and planning of the team.

# "Science is not about finding the truth. It's about the quest for truth."

#### **Marie Lindquist**

Director, Uppsala Monitoring Centre



## **National pharmacovigilance centres**

- Three new full members of the WHO PIDM: Lao People's Democratic Republic, Afghanistan, and Panama (total: 124).
- Three new WHO PIDM associate members: Malawi, Haiti, and Chad (total: 29).
- Fact-finding trips to national pharmacovigilance centres in Ghana, Morocco, Costa Rica, Mexico, Nicaragua, Guatemala, and United Arab Emirates.
- Signal detection workshop with national pharmacovigilance centres in India
- A wide-ranging survey of national pharmacovigilance centres was undertaken to gather information about their teams'
  working conditions, the medicines safety situation in countries and the awareness/usage of UMC tools and services.
   The responses will guide UMC's work in the coming years.

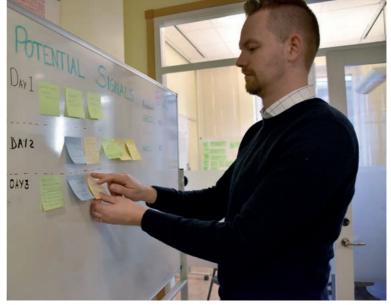


## **Products and services**

- Four releases of the WHODrug Dictionary and its subsidiary components (WHODrug Enhanced, Cross reference tool Japan, Cross reference ATC 5).
- A new version of Cross reference tool Japan was released, containing more information in order to facilitate SDTM compliance for both local and international pharma companies and CROs.
- Adoption of the WHODrug portfolio as the national standard in Japan, and recommended for use by the US FDA.
- The release of WHODrug Insight, a new browsing tool to increase efficiency and minimise errors when coding and analysing medications in clinical trials and safety reports.

## Signal detection

- 20 signals detected, assessed and published in three issues of the Signal document.
- The first vaccine signal sprint highlighted 12 potential signals. A signal sprint to ensure the relevance of UMC's signal detection work to Africa, Asia and Latin America, respectively, was undertaken.
- Research papers published stimulating international interest and recognition.
- Investigation of social media as a source of information on patient risks (WEB-RADR).



# Awareness, collaborations and training

- Two pharmacovigilance training courses (2<sup>nd</sup> Asia Pacific in India, and 18<sup>th</sup> in Uppsala).
- Webinars for VigiFlow, VigiLyze, and vigiGrade, in English, Russian, Spanish, Arabic, and French.
- Regular meetings between WHO-HQ and WHO CCs, including UMC.
- Participating in meetings and conferences, e.g.
  ISoP Annual Meeting (Czech Republic), ICPE Annual
  Meeting (USA), OHDSI (Observational Health Data
  Sciences and Informatics) (USA), CDISC (Clinical Data
  Interchange Standards Consortium) (USA), 5<sup>th</sup> China
  Pharmacovigilance Conference (China), WHO
  Technical Briefing Seminar (WHO, Geneva), 2<sup>nd</sup>
  national pharmacovigilance conference (Eritrea),
  WHO National Centres Meeting in India (which
  included organizing the pre-meeting day).
- Analysis of patient reports in VigiBase with vigiPoint presented at the Lareb Conference on Patient Reporting.
- Continued development and promotion of UMC's YouTube channel and Take&Tell.
- Launch of new design and format of Uppsala Reports.
- Continued development and promotion of UMC's social media channels Twitter, Facebook, and LinkedIn





## Safety data and reporting

- Reports in VigiBase passed 13 million.
- Reports from low- and middle income countries (LMICs) passed 1.5 million.
- VigiAccess continues offering public access to aggregated safety data from VigiBase.
- Implementation of updated vigiGrade report completeness and quality scoring.
- Implementation of eReporting in additional countries (e.g., Uruguay, Uganda, Sierra Leone).
- More than 230 search requests received from national centres and other enquirers, with 160 resulting in data being sent out.

## This year in figures

International data pooled in VigiBase is the core source for transforming safety data into knowledge and safer use of medicines. It is part of UMC's mission to find ways of increasing knowledge and to share it with member countries. In order to improve the usefulness of VigiBase, we measure the quantity, quality, and frequency of reports and help countries to improve the data they contribute.

However, it is important to keep in mind that a single report, even with limited information (low vigiGrade completeness score), and with a time delay in submission to VigiBase, may still be of relevance to the WHO PIDM and for contributing to a global patient safety culture. Here you will find statistics about VigiBase content as well as the implementation and use of UMC products.

All data presented covers the period 1 July 2015 to 30 June 2016, unless otherwise stated.

## **Quantity of ICRS reporting in VigiBase**

## Number of ICRS reporting in VigiBase

VigiBase contains 13,208,000 ICSRs – an increase of 18% (1.984 million ICSRs) over the past year.

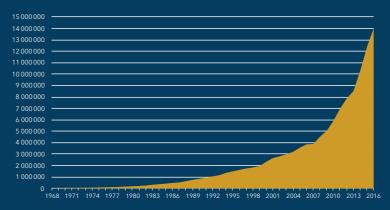


Figure 1. VigiBase cumulative increase.

## **Contribution from LMICs** to VigiBase

11.5% of the ICSRs in VigiBase come from low- and middle-income countries (LMICs - World Bank classification 2015). During the past year the number of ICSRs from LMICs increased by 32%.

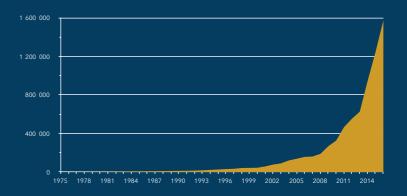
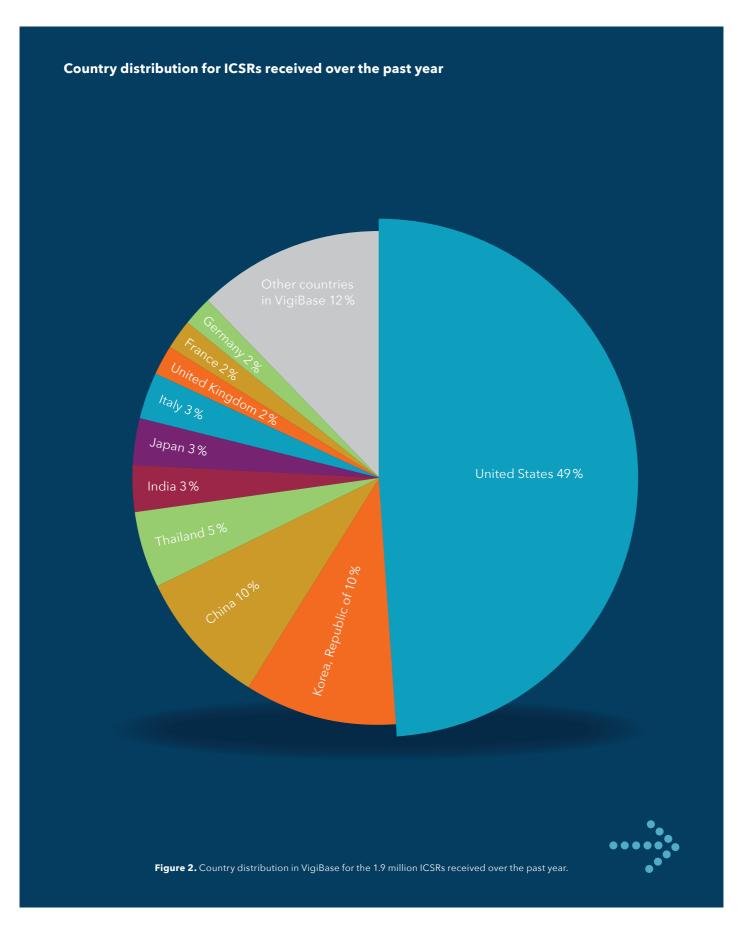


Figure 2. ICSRs from LMICs in VigiBase, as of 2015 the total is 1,513,215.



## ICSRs per million inhabitants and year

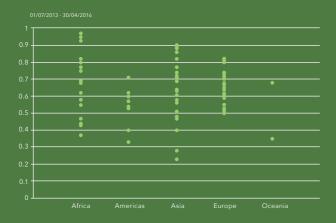


Figure 4. ICSRs received in VigiBase 2011-2016 average (to compensate for year to year fluctuations).

## **Quality of ICSR reporting**

vigiGrade completeness score is a UMC method to measure the amount of clinically relevant information in an ICSR as it appears in VigiBase. A high completeness score does not necessarily reflect the value of a report for signal detection; it is a measurement only of the likelihood of finding relevant information in a report.

## vigiGrade completeness score per country and region

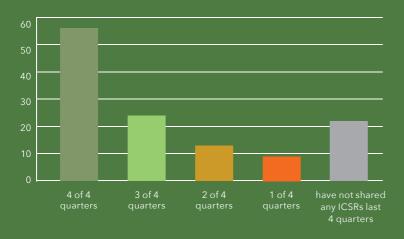


**Figure 5.** Average completeness score per country grouped by region. Each dot represents one country that has shared 100 or more ICSRs in VigiBase over the past year (1 July 2015 to 30 June 2016). Of 82 countries that have submitted 100 or more ICSRs, 70 countries (85%) have an average completeness score of 0.5 or higher.

## **Frequency of ICSR reporting**

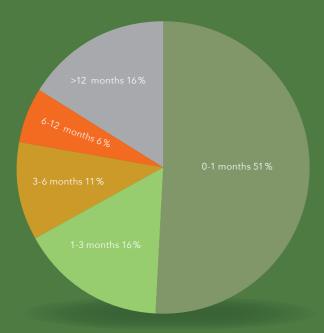
Frequent submissions of new ICSRs are critical to detect signals and take appropriate action at an early stage. Member countries are expected to submit ICSRs to UMC on a regular basis; preferably more than once a month, but at least every quarter.

## Number of countries sharing ICSRs in VigiBase, by quarter



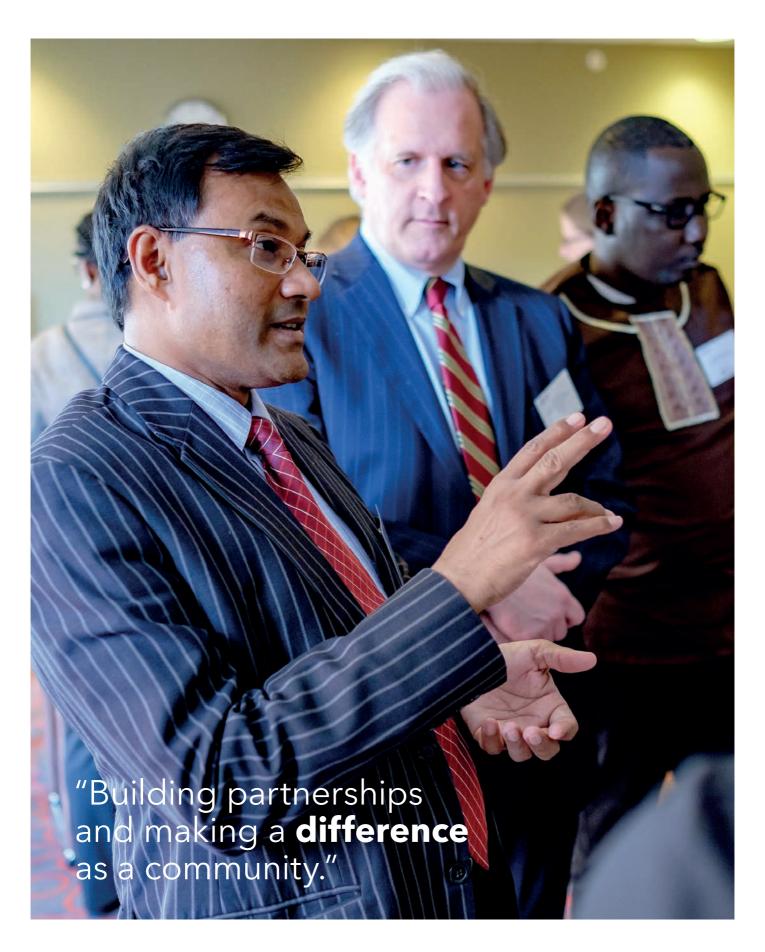
**Figure 6.** 56 countries (45% of all Full Member countries) have shared data in VigiBase all four quarters during the period 1 July 2015 to 30 June 2016.

#### Time since last submission



**Figure 7.** Countries distributed according to time elapsed since last submission of ICSRs to VigiBase, as of 30 June 2016.



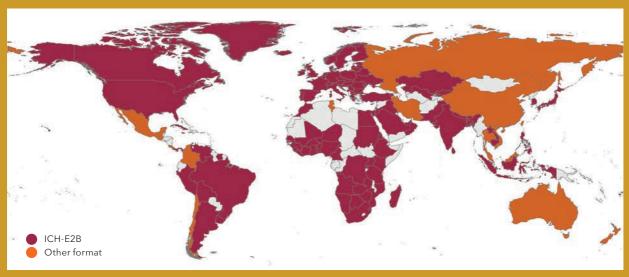


## **Tools**

### VigiFlow contribution to VigiBase

Globally, 74 National Centres use VigiFlow as their ICSR management system. In total, 480,485 ICSRs have been submitted to VigiBase from VigiFlow countries. During the year, five countries chose it as their data management system.

### **ICSR Reporting Format**



**Figure 8.** Out of 124 official member countries, 107 countries use the recommended international standard format ICH E2B. 16 countries use other reporting formats.

## New members

## **WHO Programme for International Drug Monitoring**



**Figure 9.** Three new countries (Lao People's Democratic Republic, Afghanistan, Panama) joined the WHO PIDM as Full Members, along with three new Associate Members (Malawi, Haiti, Chad) between 1 July 2015 and 30 June 2016.

## 2016-2017 in focus

In the coming year we will continue our research into new and improved methodologies to identify, analyse and explain safety issues, from all available sources of information. We will employ and evaluate novel analytical methods in routine signal detection and broaden the focus from identifying first signals to exploring why particular patients are harmed.

Through identification of risk groups, drug interactions, and molecular predictors of drug-induced harm, UMC can help prevent harm to patients from treatments available today and inform the development of better treatments for the future. In parallel, our scope will continue to move beyond adverse drug reactions (directly linked to the compound itself) to medication errors, drug resistance, and harm from substandard or counterfeit medicines.

UMC will continue to promote good health communication practices and develop tools that support positive behaviour changes in communities around the world. By creating tools that appeal to lay audiences,

UMC provides national centres with practical resources easily adaptable to their local needs.

Through our team of pharmacovigilance specialists, and in close collaboration with WHO and other Collaborating Centres, we will continue to support countries to develop their pharmacovigilance systems and our services will continue to adapt to their needs. UMC aims to develop its training and education capability to reach as wide an audience as possible, and to work closely with WHO colleagues, public health programmes, academic institutions, and donor organisations to support sustainable, high quality pharmacovigilance systems and practices for all populations.

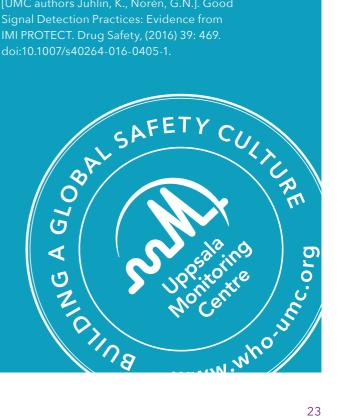
We shall continue to maintain and develop our products and services and to extend our knowledge, skill, and technology. An important priority is to develop strategic partnerships with regulators, donor organisations, and other influential stakeholders to ensure the continued growth of pharmacovigilance in the world.



## **UMC** publications

- 1. Ampadu, H.H., Hoekman, J., de Bruin, M.L, Pal, S.N., Olsson, S., Sartori, D., Leufkens, H.G.M., Dodoo, A.N.O. Adverse Drug Reaction Reporting in Africa and a Comparison of Individual Case Safety Report Characteristics Analyses of Spontaneous Reports in VigiBase. Drug Safety, DOI 10.1007/s40264-015-0387-4.
- 2. Caster, O., Edwards, I.R. Quantitative benefitrisk assessment of methylprednisolone in multiple sclerosis relapses. BMC Neurology,
- Pharmacovigilance is... Vigilance. Drug Safety, April 2016, Volume 39, Issue 4, pp281-285.
- 4. Hill, G., Pal, S., et al. Experiences and Lessons from Implementing Cohort Event Monitoring Programmes for Antimalarials in Four African Countries: Results of a Questionnaire-Based Survey. Drug Safety, 2015, DOI 10.1007/s40264-015-0331-7.
- 5. Hugman, B, Perspectives on Risk Communication and Gender Issues (Chap 18) and Risk Communication and Specific Medicines for Women (Chap 19), In: Harrison-Woolrych, M (ed), Medicines for Women, Adis Press (2015).
- 6. Low Yen, S., Caster, O., Bergvall, T., Fourches, Johnson Syndrome. Journal of the American Medical Informatics Association, DOI: http:// dx.doi.org/10.1093/jamia/ocv127 ocv127. Published 24 October 2015.

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- Maina, M., Yotebieng, M., Kumarasamy, N., Freeman, A., de Rekeneire, N., Duda, S.N., Breitstein, P. Targeted Spontaneous Reporting: Assessing Opportunities to Conduct Routine Pharmacovigilance for Antiretroviral Treatment on an International Scale. Drug Safety, DOI 10.1007/s40264-016-0434-9.
- Seabroke, S., Candore, G., Juhlin, K., Quarcoo, Performance of Stratified and Subgrouped Disproportionality Analyses in Spontaneous Databases. Drug Safety, April 2016, Volume 39, Issue 4, pp 355-364.
- 10. Wisniewski, A.F.Z., Bate, A., Bousquet, C. et al [UMC authors Juhlin, K., Norén, G.N.]. Good Signal Detection Practices: Evidence from



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## **About Uppsala Monitoring Centre**

**Uppsala Monitoring Centre** advances the science of pharmacovigilance and inspires patient safety initiatives all over the world. As an independent, non-profit foundation, we engage stakeholders who share our vision and collaborate to build a global patient safety culture.

As a leader in the research and development of new scientific methods, we explore the benefits and risks of medicines to help minimize harm to patients, and offer products and services used by health authorities and life-science companies worldwide.

Our unique expertise makes us an organisation with the capacity to transform patient safety from an ambition into a reality.

For almost 40 years, we have provided scientific leadership and operational support to the WHO Programme for International Drug Monitoring, expanding the global pharmacovigilance network to reach more than 95% of the world's population.

## INSPIRE, ENGAGE, TRANSFORM,



