



Dr Lembit Rägo  
Secretary-General  
of CIOMS

# CIOMS activities during 2021

- ❑ Introduction
- ❑ What has happened during 2021?
- ❑ CIOMS Working Groups in 2021 and 2022
- ❑ Discussion and conclusions



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# Introduction

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Council for  
International  
Organizations of  
Medical  
Sciences



Founded in 1949 by WHO and UNESCO

In official relations with WHO and  
UNESCO associated partner  
ICH Observer since 2016

President - Professor Hervé Le Louet (since 2016)

Secretary-General – Dr Lembit Rägo (since 2016)

## Mission Statement

**CIOMS mission is to advance public health through guidance on health research including ethics, medical product development and safety**

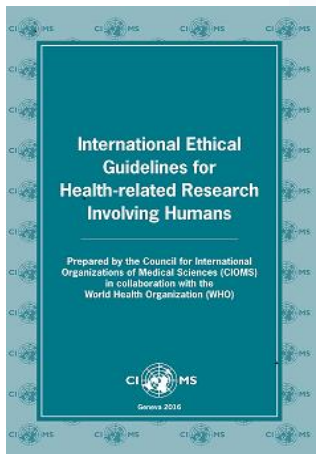


# Major areas of work

## Bioethics

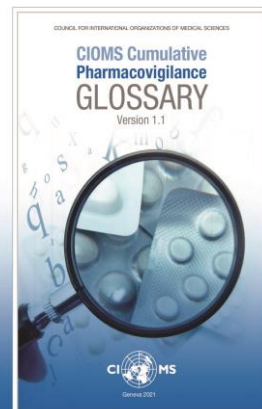
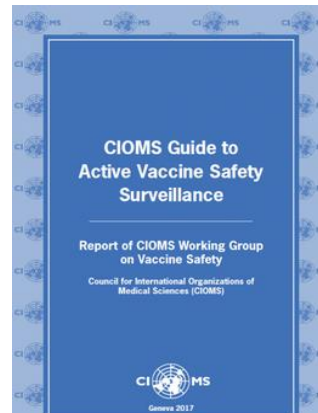
Since 1967; 1. CIOMS Round Table Conference "Biomedical Science and the dilemma of Human Experimentation") Issuance of significant guidelines; latest revision 2016

- Focus on "low and middle income countries"; translated into many languages including Chinese, Spanish, Japanese, Russian



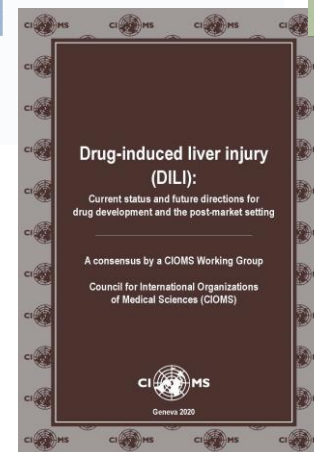
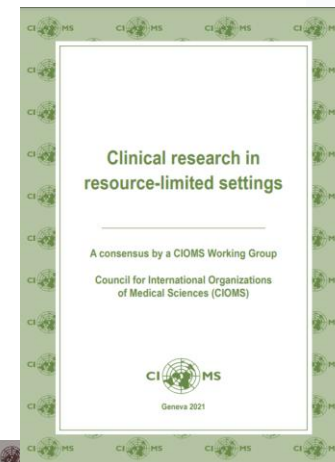
## Pharmacovigilance

- 1986 first PV Working Group, 13 more working group reports until today
- Several ICH Guidelines are based on results of CIOMS Working Groups
- Cumulative Glossary 2021



## Product Development

- Trends and Prospects in Drug Research and Development, Proceedings of the 11<sup>th</sup> CIOMS Round Table Conference, Geneva, Switzerland, 8-9 December 1977. Ed. Z. Bankowski, J.F. Dunne, published by Scrip World Pharmaceutical News, London, 1978.



- ❑ The COVID-19 pandemic has had a huge global impact
  - We all needed to adapt to new realities and keep going
- ❑ We have introduced new ways of working and in 2020 and 2021 only virtual meetings took place - in 2021 16 virtual full WG meetings, numbers for editorial group or WG sub-group meetings is much higher
- ❑ In this report we try to give some snapshots about what has happened in 2021, also beyond WGs
- ❑ COVID-19 has affected our work in 2020/2021, but also affects it in 2022 and beyond
- ❑ When can we return to the situation before COVID-19? We will never return to exactly the same, but let us hope that from autumn 2022 we will have a mostly restrictions-free world

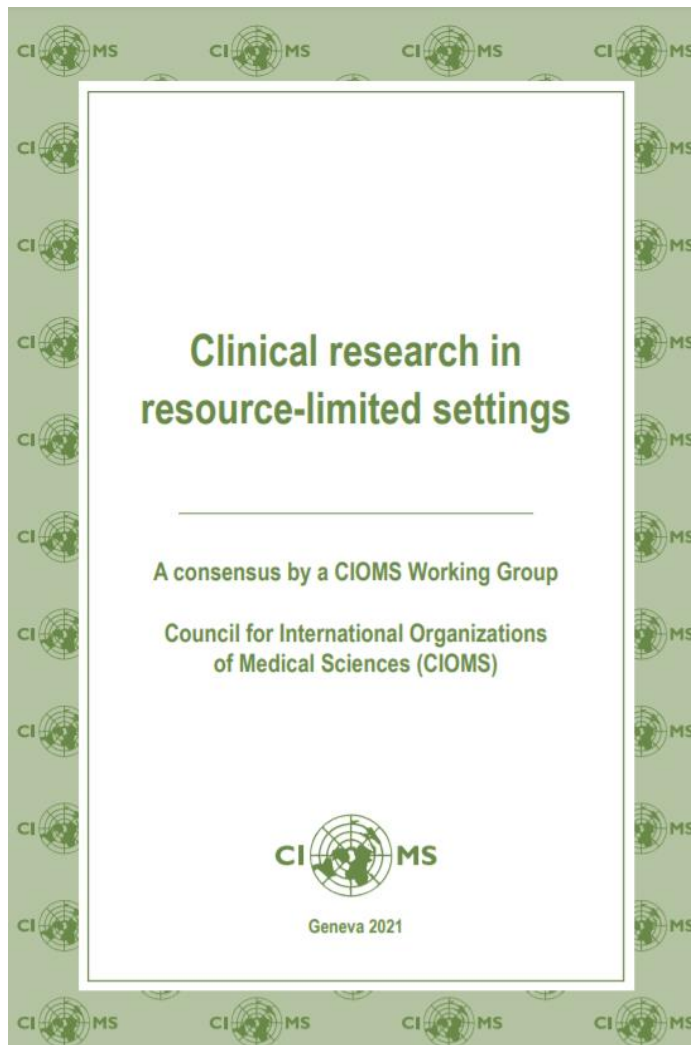


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**Some highlights from 2021**

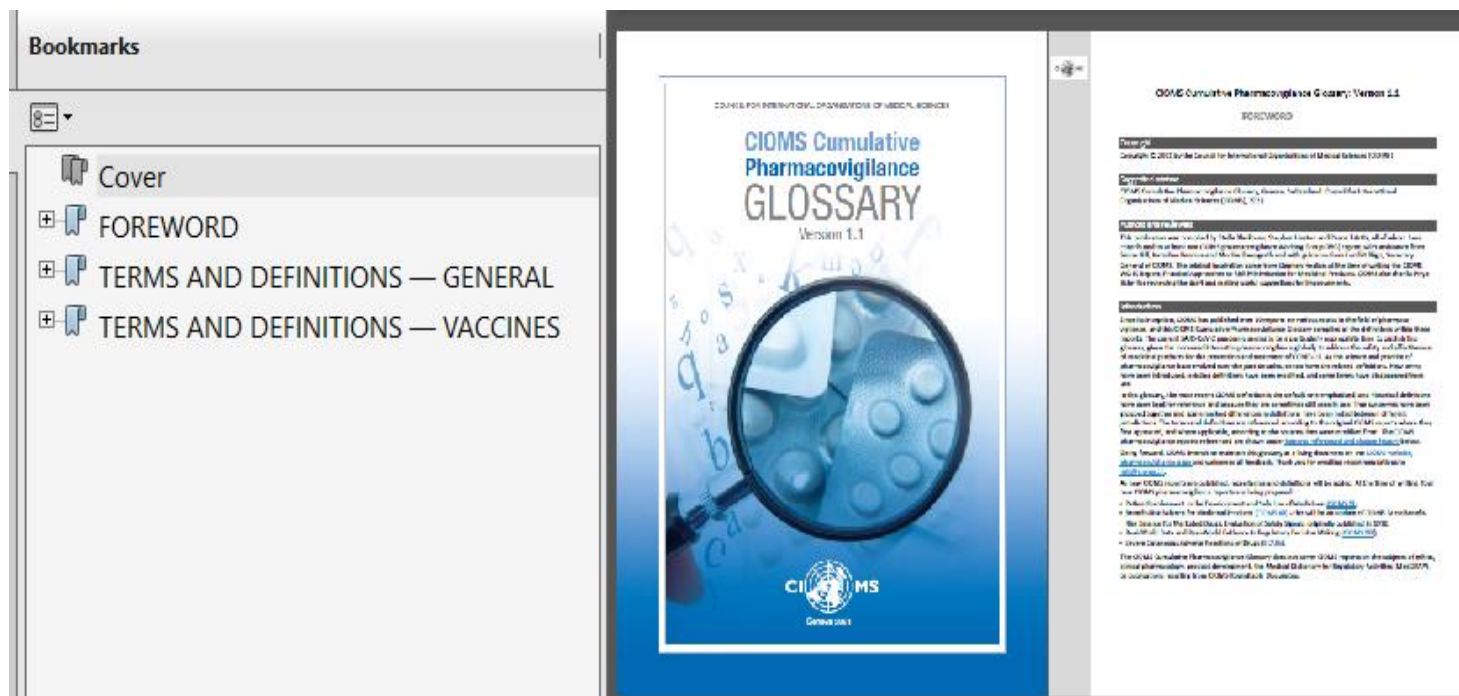
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CIOMS International  
Working Group on *Clinical  
Research in Resource-  
limited Settings* consensus  
report





## CIOMS Cumulative Pharmacovigilance Glossary, Versions 1.0 and 1.1



## Conference announcement



### AASLD-FDA 2021 Conference on Drug-Induced Liver Injury (DILI)

Virtual conference, 20-22 April 2021 | [Conference website](#)

This online conference will address new developments, tools and assessment strategies in patients with underlying liver disease or cancer and in the setting of the COVID-19 pandemic. It is expected to attract an international audience of clinicians, scientists and regulatory experts.

The moderators and speakers include several members of the former CIOMS Working Group on Drug-Induced Liver Injury (DILI). In a session entitled *Perspectives in the development of best practices for different DILI scenarios*, four presentations will be dedicated to components of the 2020 [CIOMS DILI Working Group report](#).

### DIA 2021 Global Annual Meeting: Session held 30 June 2021

Patient-Focused Benefit-Risk Assessment and Risk Management: Methodology for Engaging with Patients – What has been Learned?

Updates from the organizations of CIOMS Working Group members:



**Juan Garcia Burgos**  
EMA  
(Chair)



**Lembit Rägo**  
CIOMS



**Theresa Mullin**  
FDA



**Talia Lacroix**  
Health Canada



**François Houyez**  
Eurordis

## Joint CIOMS/Uppsala Monitoring Centre (UMC) training modules based on CIOMS DILI WG report (started 2021, finalized 2022)

[Courses](#)[About us](#)[Contact](#)[FAQ](#)[Log in](#)[< English](#)

### Drug induced liver injury (DILI)

[Course](#)

No access code required

[Enrol](#)[About](#) [Modules](#) [Certificates](#)

This e-learning course is the first fruit of cooperation between the UMC and the Council for International Organizations of Medical Sciences on an important but complex topic in pharmacovigilance.

### Target audience

The course is based on the sections of the CIOMS consensus document most relevant to the post-marketing setting, and clinical care. V... already have basic training and practical experience in pharmacovigilance. It is also likely to be of benefit to members of national pharm...

### Course syllabus

- What is DILI
  - Understand the meaning of DILI and be able to classify cases according to categories and severity.
- Assessing DILI cases
  - Learn to assess DILI case reports and enter valid data on the diagnosis, severity and causality into an ICSR management system.
- Post-marketing surveillance for DILI
  - Know the sources and nature of post-marketing surveillance data and be able to use these to build and assess case series.
- Clinical care
  - Know and understand the different levels of advice about monitoring patients taking hepatotoxic medicines and clinical manifestations.
- Liver injury attributed to herbal and dietary supplements
  - Evaluate ICSRs of herbal and dietary supplements incorporating specific information needed for these preparations.

### Certificate

Each lesson is followed by a quiz that must be passed to be able to move forward. A certificate is awarded when you have passed the lessons and successfully completed the full course.

### April 2022

Enrolled learners: 11

Completed the course and received a certificate: 10

### May 2022

Enrolled learners: 270

Completed the course and received a certificate: 130

In 2021 four quarterly regular NL editions were produced + one specialized issue dedicated to the Uppsala Monitoring Centre (UMC)



Page	Quick links
1	<b>Public consultation ongoing:</b> CIOMS WG report on clinical research in resource-limited settings
2	<b>2020 CIOMS award for best student paper</b>
3	<b>Update on CIOMS Working Groups:</b>   CIOMS cumulative glossary published
5	<b>Events and publications:</b>   What's new with COVID-19?   Conference announcement
7	<b>News from the CIOMS Secretariat:</b> CIOMS cited   Find us on the web

## Public consultation ongoing

### Report of the CIOMS Working Group on Clinical Research in Resource-Limited Settings

More clinical research is needed in resource-limited settings to cater for the health needs of these

After three years of work, the CIOMS Working Group on Clinical Research in Resource-Limited



Page	Quick links
1	<b>Just published:</b> Clinical research in resource-limited settings   CIOMS pharmacovigilance glossary Version 1.1
3	<b>Events and publications:</b> WHO   ICH   What's new with COVID-19
5	<b>Update on CIOMS Working Groups</b>
6	<b>News from the CIOMS Secretariat:</b> XXIV CIOMS General Assembly   CIOMS cited   Find us on the web

## Just published

**Clinical research in resource-limited settings**  
CIOMS Working Group report



Page	Quick links
2	<b>Events</b> Rudolf Buchheim 200 conference   Safety signals for COVID-19 vaccines   Extraordinary ICDRA   Other events in brief
3	<b>Publications</b> Pharmaceutical Medicine   Artificial intelligence   Human genome editing
6	<b>What's new with COVID-19?</b>
6	<b>Publications (ct'd)</b> A call for agreeing on terminology and good practices   CIOMS cited
7	<b>News from the CIOMS Secretariat</b> Overview of CIOMS Working Groups   CIOMS student award

We open this newsletter with some impressions from a "real-life" conference, the first after almost two years of COVID-19 restrictions for many of those who attended: The Rudolf Buchheim 200 conference held in Tartu, Estonia ([see next page](#)).



Photos kindly provided by the conference Organizing Committee



## What's on @ CIOMS

COUNCIL FOR INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES



WWW.CIOMS.CH

Special Newsletter | 9 November 2021



## Making medicines safer for patients everywhere

This is the fourth of a series of special newsletters that describe the context of CIOMS activities and the work of its member organizations and partners. It describes what the Uppsala Monitoring Centre (UMC) is doing to support and promote patient safety through effective and global pharmacovigilance practice.

CIOMS thanks the UMC Team for their collaboration and support in producing this newsletter. For more information about the UMC and its activities, please contact: [info@who-umc.org](mailto:info@who-umc.org).

### Quick links

- 2 [Editorial](#)
- 3 [UMC as a WHO Collaborating Centre](#)
- 4 [A new organization for a new era](#)
- 5 [CIOMS and UMC: Advancing medicines safety together](#)
- 6 [Opportunities and perspectives](#)

The vision of the Uppsala Monitoring Centre (UMC) is a world where all patients and health professionals make wise therapeutic decisions in their use of medicines.



UMC uses the science of **pharmacovigilance** to explore and understand the risks and benefits of medicines.



## 2021 CIOMS student award

The 2021 CIOMS award of US\$ 1500 for the best scientific article published by a student in the areas of pharmacovigilance or research ethics goes to **Gilbert Lazarus** for his paper:

Lazarus G, Tjoa K, Iskandar AWB, et al. **The effect of human immunodeficiency virus infection on adverse events during treatment of drug-resistant tuberculosis: A systematic review and meta-analysis.** PLoS One. 2021 Mar 4;16(3):e0248017. doi: 10.1371/journal.pone.0248017.

Gilbert is a fifth-year undergraduate medical student at the Faculty of Medicine of the Universitas Indonesia. He is aspiring to become a physician-scientist in the field of internal medicine. His research focus revolves around epidemiology and evidence-based medicine, with special interests in the areas of cancer immunology and treatment, COVID-19 and tropical infectious diseases, and metabolic syndrome. He has authored and co-authored more than a dozen peer-reviewed journal articles, has himself peer-reviewed publications for several international journals, and has served as editor-in-chief for the Journal of Asian Medical Students' Association (JAMSA).

 **Applications for the 2022 CIOMS award are welcome. [Read more...](#)**



*Gilbert's ambition is to alleviate the devastating burden of communicable and non-communicable diseases in developing regions. During the COVID pandemic, he and his colleagues launched a nationwide research project to explore the potential involvement of medical student volunteers in Indonesia to help mitigate the crisis.*

## Find us on the web



### Top 3 countries (Q3, 2021)

<b>1</b>	United States	5 830
<b>2</b>	India	3 578
<b>3</b>	China	2 764
<b>Total visitors</b>		<b>25 060</b>

### Top 3 downloads (Q3, 2021)

<b>1</b>	CIOMS I form	2 343
<b>2</b>	Cumulative Glossary Version 1.1	611
<b>3</b>	CIOMS 2016 Ethical Guidelines	503
<b>Total downloads</b>		<b>8 056</b>

*As at 27 September 2021. Numbers of page views and visitors extrapolated to 30 September.*

- ❑ To be more efficient in the future we need to know who and how uses our resources
  
- ❑ In 2021 we started to improve website in order to have additional functions such as
  - 1) Registering person profiles who want to download CIOMS documents
  
  - 2) Creating regular automatic reports about approaches to different parts of the website, downloads of individual CIOMS reports etc.



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# CIOMS Working Groups

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- ❖ Clinical Research in Resource-limited Settings. November 2017
- ❖ Patient Involvement in the Development and Safe Use of Medicines. CIOMS WG XI. Started April 2018
- ❖ MedDRA Labelling Groupings. Started April 2019
- ❖ Benefit-Risk Balance for Medicinal Products. CIOMS WG XII. Started September 2019
- ❖ Real-World Data and Real-World Evidence in Regulatory Decision-Making. CIOMS WG XIII. Started March 2020



# New CIOMS Working Groups started in 2021

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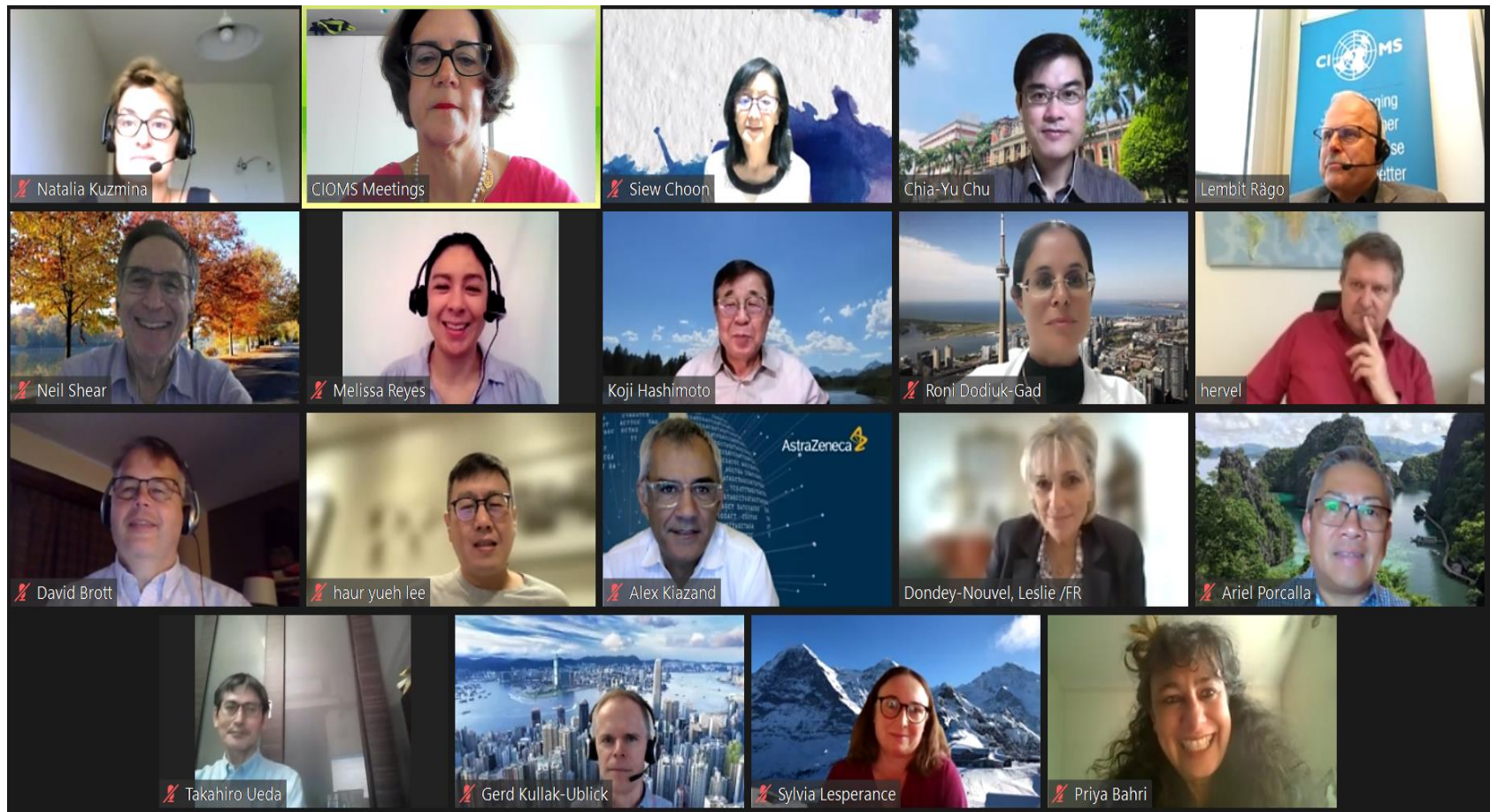


- ❖ Severe Cutaneous Adverse Reactions (SCARs). February 2021
- ❖ Recommended Standards of Education and Training for Health Professionals Participating in Medicines Development. April 2021
- ❖ Good Governance for Research Institutions. July 2021

# Virtual meetings: main tool for making progress in 2021



## SCARs virtual WG meeting picture:



# New Working Groups in 2022

- ❖ CIOMS WG XIV: Artificial Intelligence in pharmacovigilance. First meeting (hybrid of in person/virtual) during 18-19 May 2022







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## Discussion and Conclusions

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