EU Vaccine Monitoring Platform What is it, and how can it inform HCPs, patients, and the public, on the benefit/risk of vaccines

Joint PCWP-HCPWP meeting
03 July 2024

Catherine Cohet, Real-World Evidence (RWE) Workstream, Data Analytics & Methods Task Force

Alessandra Buoninfante, Public Health Threats

On behalf of the VMP Secretariat

Emergency Task Force (ETF) established by Reg. EU 123/2022

Expert advisory body of EMA for emergencies and preparedness

Co-Chairs: EMA representative and CHMP vicechair

Representatives from groups **based on expertise**:

Scientific Committees (CHMP, PRAC, PDCO, CMDh) **and EMA Representatives**

Working Parties' experts on vaccinology, biologics, infectious disease treatment, biostatistics, inspection, clinical trials, scientific advice assessment

Patients and Healthcare professionals identified by PCWP and HCPWP to bring the views of their respective communities

Clinical trial experts from various EU Member States (Clinical Trials Advisory Group (CTAG) and Clinical Trials Coordination Group (CTCG))

Additional experts and observers from academia, EU national or international regulators, EU bodies

https://www.ema.europa.eu/en/committees/working-parties-other-groups/emergency-task-force-etf

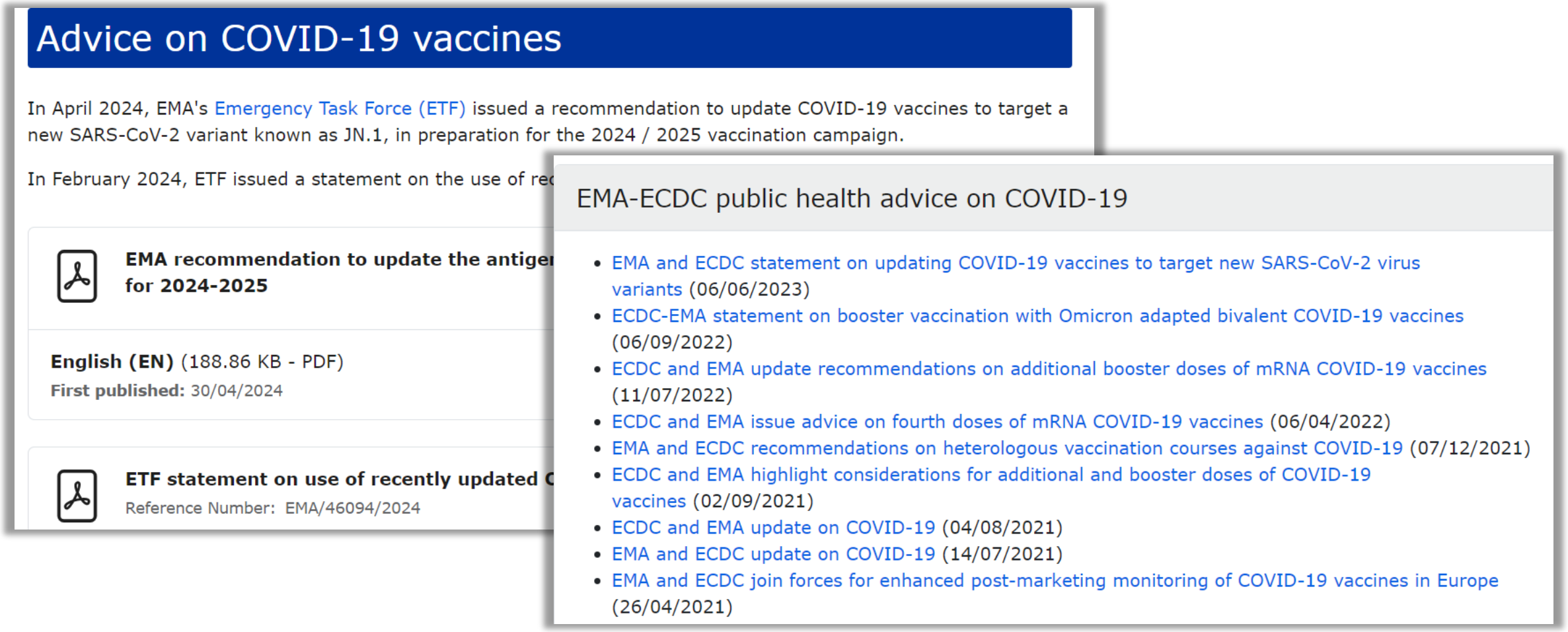
ETF responsibilities

- Providing **scientific advice** to developers
- Reviewing scientific data
- Engaging in preliminary discussions with developers
- Offering scientific support to facilitate **clinical trials** in the EU

- Providing scientific **recommendations** on the use of medicines prior to their authorisation
- Cooperating with European and international organisations

- Supporting the work of EMA's **scientific committees**
- **Making use of real-world evidence to support preparation for crises and responding to them**

Impact on public health: ETF recommendations



Advice on COVID-19 vaccines

In April 2024, EMA's Emergency Task Force (ETF) issued a recommendation to update COVID-19 vaccines to target a new SARS-CoV-2 variant known as JN.1, in preparation for the 2024 / 2025 vaccination campaign.

In February 2024, ETF issued a statement on the use of rec

EMA recommendation to update the antiger for 2024-2025

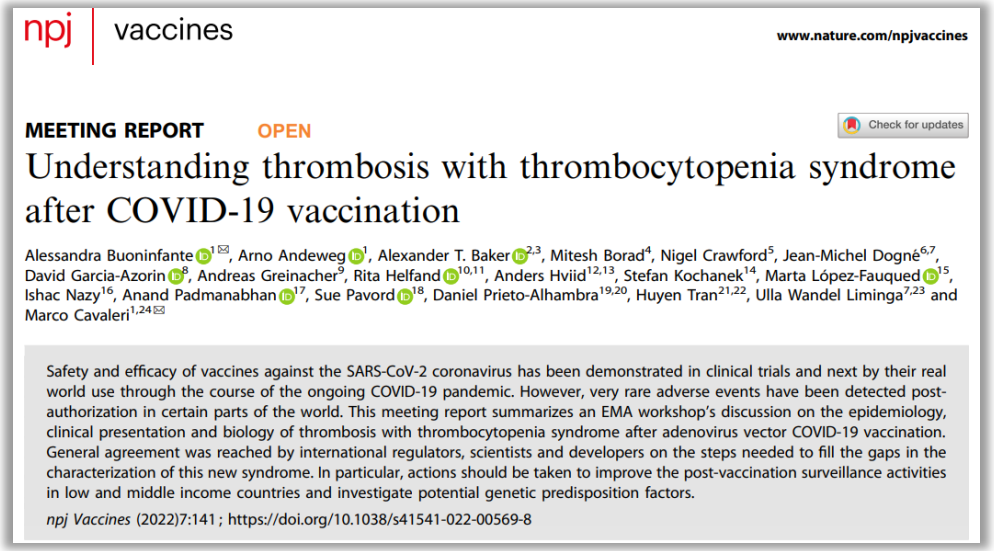
English (EN) (188.86 KB - PDF)
First published: 30/04/2024

ETF statement on use of recently updated C
Reference Number: EMA/46094/2024

EMA-ECDC public health advice on COVID-19

- EMA and ECDC statement on updating COVID-19 vaccines to target new SARS-CoV-2 virus variants (06/06/2023)
- ECDC-EMA statement on booster vaccination with Omicron adapted bivalent COVID-19 vaccines (06/09/2022)
- ECDC and EMA update recommendations on additional booster doses of mRNA COVID-19 vaccines (11/07/2022)
- ECDC and EMA issue advice on fourth doses of mRNA COVID-19 vaccines (06/04/2022)
- EMA and ECDC recommendations on heterologous vaccination courses against COVID-19 (07/12/2021)
- ECDC and EMA highlight considerations for additional and booster doses of COVID-19 vaccines (02/09/2021)
- ECDC and EMA update on COVID-19 (04/08/2021)
- EMA and ECDC update on COVID-19 (14/07/2021)
- EMA and ECDC join forces for enhanced post-marketing monitoring of COVID-19 vaccines in Europe (26/04/2021)

Information on the safety of COVID-19 vaccines



npj | vaccines

www.nature.com/npjvaccines

MEETING REPORT OPEN

Check for updates

Understanding thrombosis with thrombocytopenia syndrome after COVID-19 vaccination

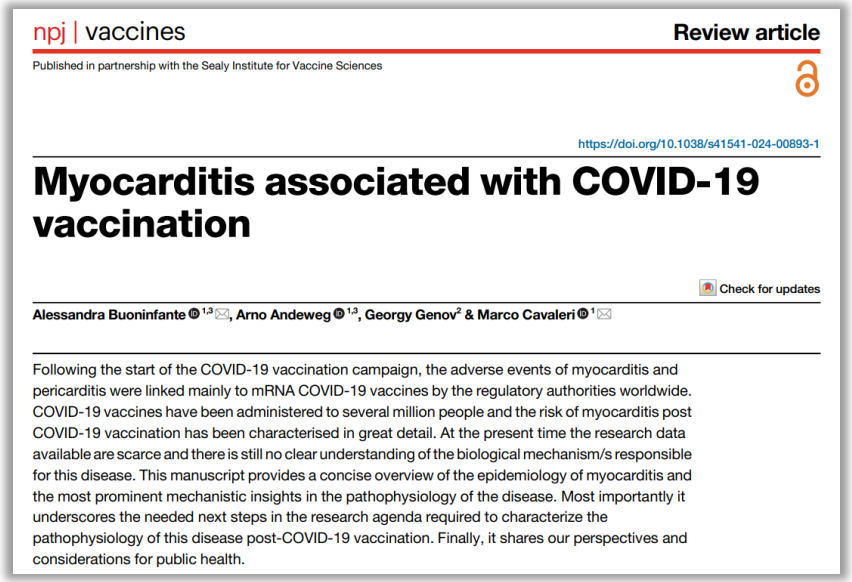
Alessandra Buoninfante[1✉], Arno Andeweg[1], Alexander T. Baker[2,3], Mitesh Borad[4], Nigel Crawford[5], Jean-Michel Dogné[6,7], David Garcia-Azorin[8], Andreas Greinacher[9], Rita Helfand[10,11], Anders Hviid[12,13], Stefan Kochanek[14], Marta López-Fauqued[15], Ishac Nazy[16], Anand Padmanabhan[17], Sue Pavord[18], Daniel Prieto-Alhambra[19,20], Huyen Tran[21,22], Ulla Wandel Liminga[7,23] and Marco Cavaleri[1,24✉]

Safety and efficacy of vaccines against the SARS-CoV-2 coronavirus has been demonstrated in clinical trials and next by their real world use through the course of the ongoing COVID-19 pandemic. However, very rare adverse events have been detected post-authorization in certain parts of the world. This meeting report summarizes an EMA workshop's discussion on the epidemiology, clinical presentation and biology of thrombosis with thrombocytopenia syndrome after adenovirus vector COVID-19 vaccination. General agreement was reached by international regulators, scientists and developers on the steps needed to fill the gaps in the characterization of this new syndrome. In particular, actions should be taken to improve the post-vaccination surveillance activities in low and middle income countries and investigate potential genetic predisposition factors.

npj Vaccines (2022)7:141 ; https://doi.org/10.1038/s41541-022-00569-8

- EMA workshop on thrombosis with thrombocytopenia syndrome – 27 June 2022

https://www.ema.europa.eu/en/events/ema-workshop-thrombosis-thrombocytopenia-syndrome



npj | vaccines

Review article

Published in partnership with the Sealy Institute for Vaccine Sciences

https://doi.org/10.1038/s41541-024-00893-1

Myocarditis associated with COVID-19 vaccination

Check for updates

Alessandra Buoninfante[1,3✉], Arno Andeweg[1,3], Georgy Genov[2] & Marco Cavaleri[1✉]

Following the start of the COVID-19 vaccination campaign, the adverse events of myocarditis and pericarditis were linked mainly to mRNA COVID-19 vaccines by the regulatory authorities worldwide. COVID-19 vaccines have been administered to several million people and the risk of myocarditis post COVID-19 vaccination has been characterised in great detail. At the present time the research data available are scarce and there is still no clear understanding of the biological mechanism/s responsible for this disease. This manuscript provides a concise overview of the epidemiology of myocarditis and the most prominent mechanistic insights in the pathophysiology of the disease. Most importantly it underscores the needed next steps in the research agenda required to characterize the pathophysiology of this disease post-COVID-19 vaccination. Finally, it shares our perspectives and considerations for public health.

- EMA virtual workshop on myocarditis post COVID-19 vaccination - 16 January 2023

https://www.ema.europa.eu/en/events/ema-virtual-workshop-myocarditis-post-covid-19-vaccination

Monitoring medicines after authorisation to support the work of the ETF

Based on **art 20 of the new Regulation EU 123/2022** on EMA extended mandate,

the EMA shall coordinate independent monitoring studies on use, effectiveness and safety of medicines to support the work of the Emergency Task Force (ETF).

For vaccines targeting an emergency, this will be done by creating a Vaccines Monitoring Platform (VMP)


EDITORIAL

Preparing Europe for future health threats and crises – the European Medicines Agency; ensuring safe and effective medicines and medical devices

Emer Cooke[1]
1. European Medicines Agency (EMA), Amsterdam, the Netherlands

Euro Surveill. Oct 2022


BJCP British Journal of Clinical Pharmacology

EDITORIAL | Open Access

Commentary on the European Medicines Agency's extended mandate: Protecting public health in times of crisis and improving availability of medicines and medical devices

Inga Abed, Rosa Gonzalez-Quevedo, Manuela Mura, Monica Dias, Silvy da Rocha Dias, Juan García Burgos

First published: 07 November 2022 | https://doi.org/10.1111/bcp.15567

Abed I. et al. Br J Clin Pharmacol. Nov 2022

Vaccine Monitoring Platform LINK

EMA/ECDC **extended mandates** → **joint evidence generation** on vaccine use, effectiveness and safety

- Identification and prioritisation of **evidence gaps** (from regulatory procedures, national public health needs, or independent research)
- Facilitation, coordination, registration of **post-authorisation studies**
- **Independent** studies using EMA and ECDC scientific/operational infrastructures and procurement + DARWIN EU for EMA
- Identification of gaps and opportunities in the EU **infrastructure** for studies (e.g., data discoverability and use)
- **Communication** - to EU regulatory & public health decision makers (work plan, study results)
- **Funding** - contribution from the European Commission to the budget of ECDC and EMA
- **Governance** - Steering Group and Joint Secretariat

EU Immunisation and Vaccine Monitoring Board (IVMAB)

- Advice on **strategy, data sources, feasibility, methods**
- And on **interpretation** and **use** of vaccine real-world evidence (RWE)

6 regulatory experts from **EMA** Committees & ETF

National Competent Authorities

National Focal Points from all 29 EU/EEA public health authorities on vaccine-preventable diseases and immunisation (**ECDC** network)

Link to IVMAB meeting summaries

VMP Research areas

For authorised vaccines

- **Address gaps**: special populations; additional endpoints (e.g., effectiveness when authorisation based on immunogenicity); long-term effectiveness/safety
- Confirmation of the **B/R profile**: viral evolution/change in vaccine composition (COVID-19, flu); need for additional knowledge on known safety/effectiveness concerns
- Support **emergency use** with new indications (e.g., smallpox → mpox)
- Mixed **schedules** in paediatric/elderly (e.g., meningococcal/pneumococcal vaccines)

Preparedness

- Research indicates potential **development** of new vaccines
- Vaccines in development or undergoing **regulatory review**: burden of disease; background incidence rates of AESIs; research on novel/recent platforms (mRNA)

+ Methods

List of studies
vaccine-monitoring-platform-list-ema-funded-studies (europa.eu)

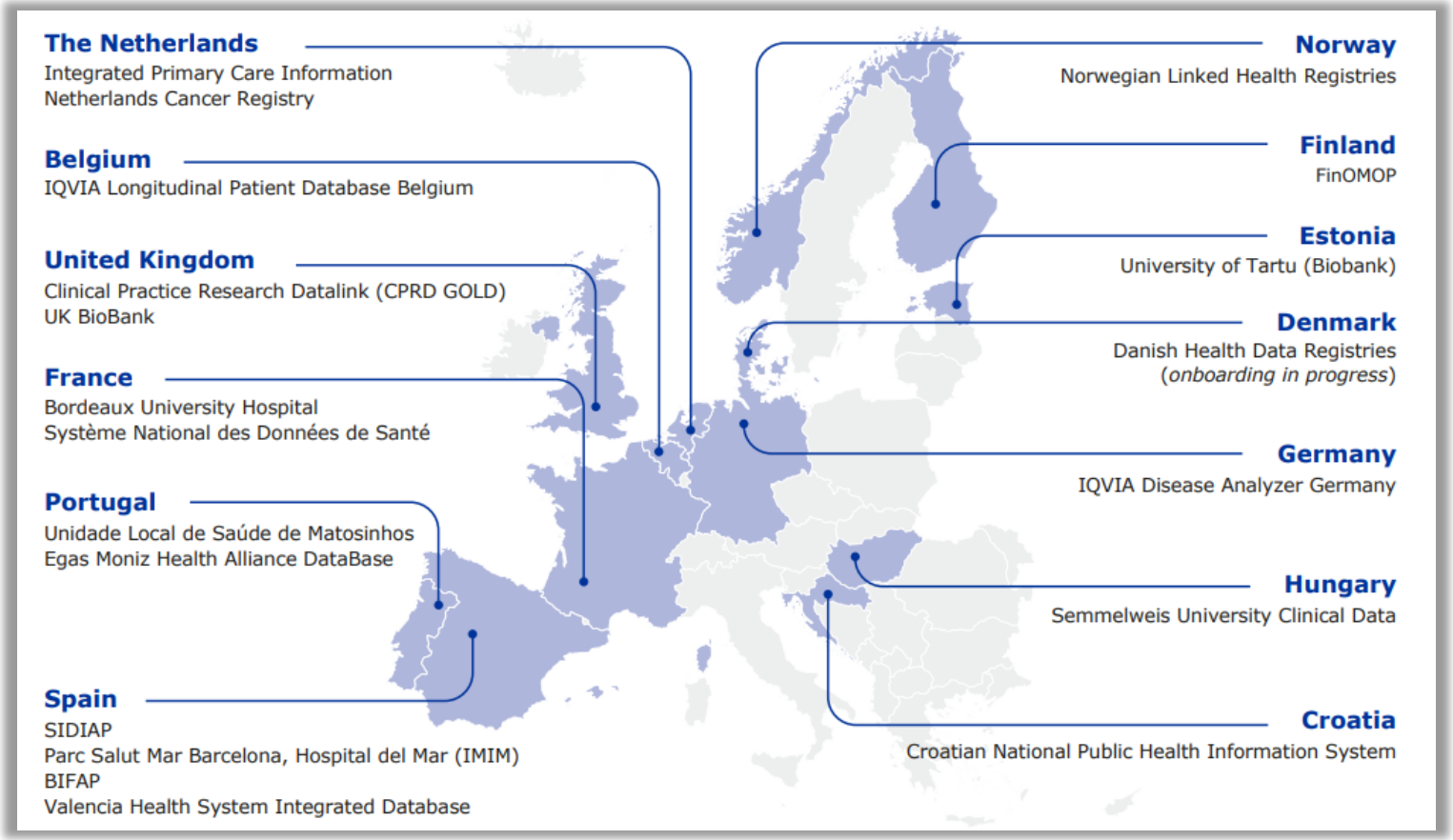
Research agenda
Vaccine Monitoring Platform (VMP) research agenda (europa.eu)

EMA pathways for RWE generation

VMP

1 DARWIN EU

- Federated network of data/expertise/services, established 2022 (2nd year completed in Feb. 2024)
- Standard analytical pipelines and codes & use of OMOP CDM, data stays local
- Access to data from ~130 million patients in 2024
- ~40 data partners by end 2025



2

Studies using in-house data sources

- Primary care EHRs (IDA Germany and IMRD UK)

VMP

3

Studies procured through EMA framework contracts

- Current FWCs to 2025
- 8 research organisations and academic institutions
- 59 data sources
- 21 EU countries
- Scientific expertise

EMA

Procured vaccine studies

Safety and effectiveness of mpox vaccination

2020 **2021** **2022** **2023** **2024**

ACCESS
Background rates AESIs Protocols

CONSIGN
Medicines in pregnancy

Natural history of **coagulopathy** and use of anti-thrombotic agents in COVID-19 patients and vaccinees

Covid-Vaccine Monitor (CVM)

Early-Covid-Vaccine Monitor (ECVM)

Benefit Risk contextualisation of COVID-19 vaccines in the EU

Association between thrombosis with thrombocytopenia syndrome (**TTS**) or **thromboembolic (TE)** events, and COVID-19 vaccines

Impact of EU label changes and regulatory communication on adenovirus vector vaccines in context of TTS: risk awareness and adherence

Comparative effectiveness of hetero- and homologous primary- and booster COVID-19 vaccination in Nordic countries

Effectiveness of heterologous and booster COVID-19 vaccination in 5 EU countries

Safety in children (myocarditis TE/CV events, IMDs)

Readiness for vaccine **safety** studies (framework of data sources and methods)

Influenza vaccine effectiveness

Effectiveness adapted COVID-19 vaccines in Nordic countries

- Safety
- Benefit/risk
- Effectiveness
- Impact

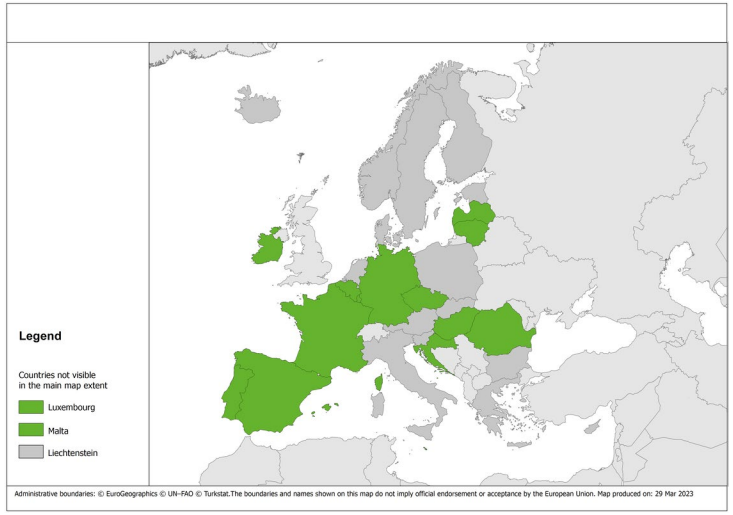
vaccine-monitoring-platform-list-ema-funded-studies

EMA vaccine studies in DARWIN EU

- Age-specific incidence rates of RSV-related disease in Europe → readiness for VE studies (completed)
- Effectiveness of COVID-19 vaccines on severe COVID-19 and post acute outcomes of SARS-CoV-2 infection → bivalent vaccines; components of long COVID (report under review)
- Effectiveness of Human Papillomavirus Vaccines (HPV) to prevent cervical cancer (analyses ongoing)
- Background incidence rates of selected vaccine adverse events of special interest (AESIs) in Europe (any vaccine; protocol under development)
- Effectiveness of COVID-19 vaccination to prevent long COVID / post-acute sequelae condition (protocol under development)

And more studies in planning to address the Vaccine Monitoring Platform (VMP) Research agenda

VEBIS (Vaccine Effectiveness Burden & Impact Studies project)
4 multi-counties studies on vaccine effectiveness



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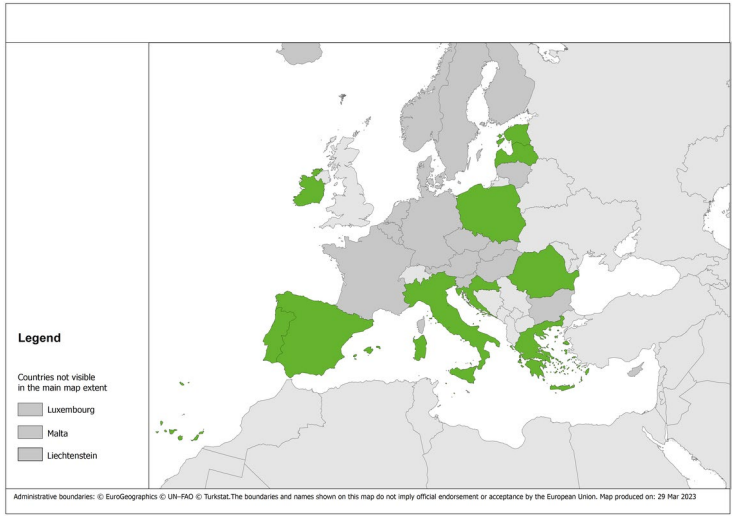
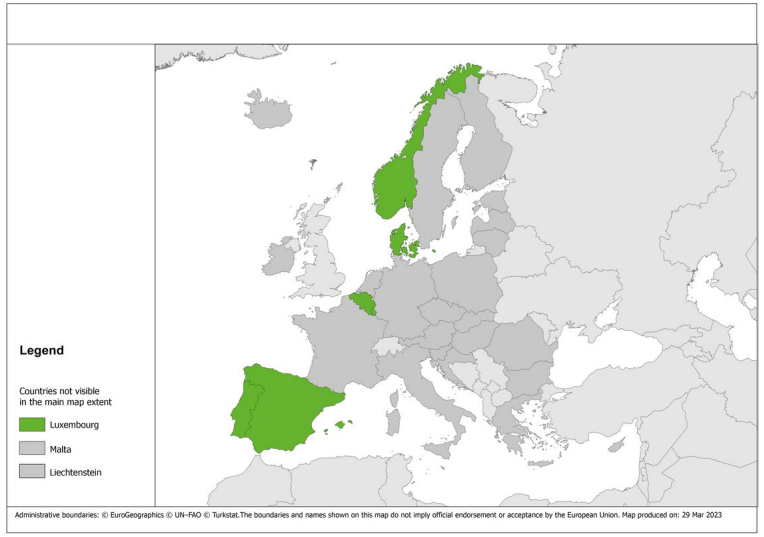
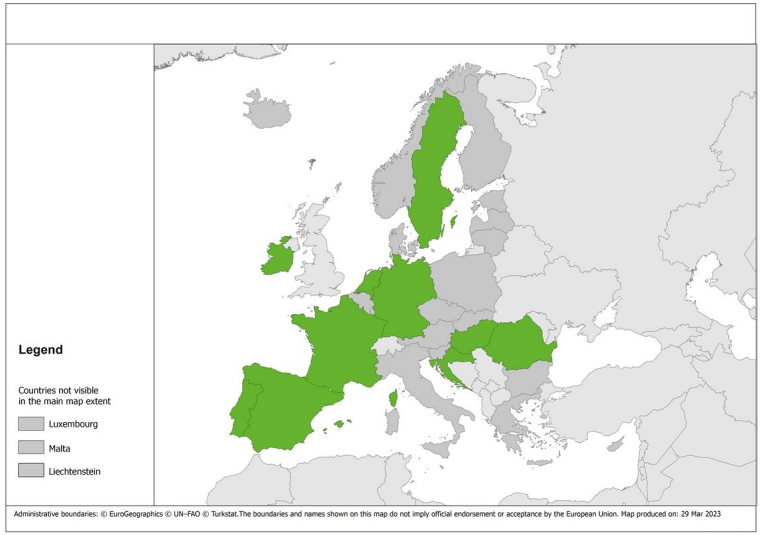


Health Care Worker cohort
COVID-19
Influenza
//
Infection



Healthcare databases/ National registries
COVID-19
//
Severe disease



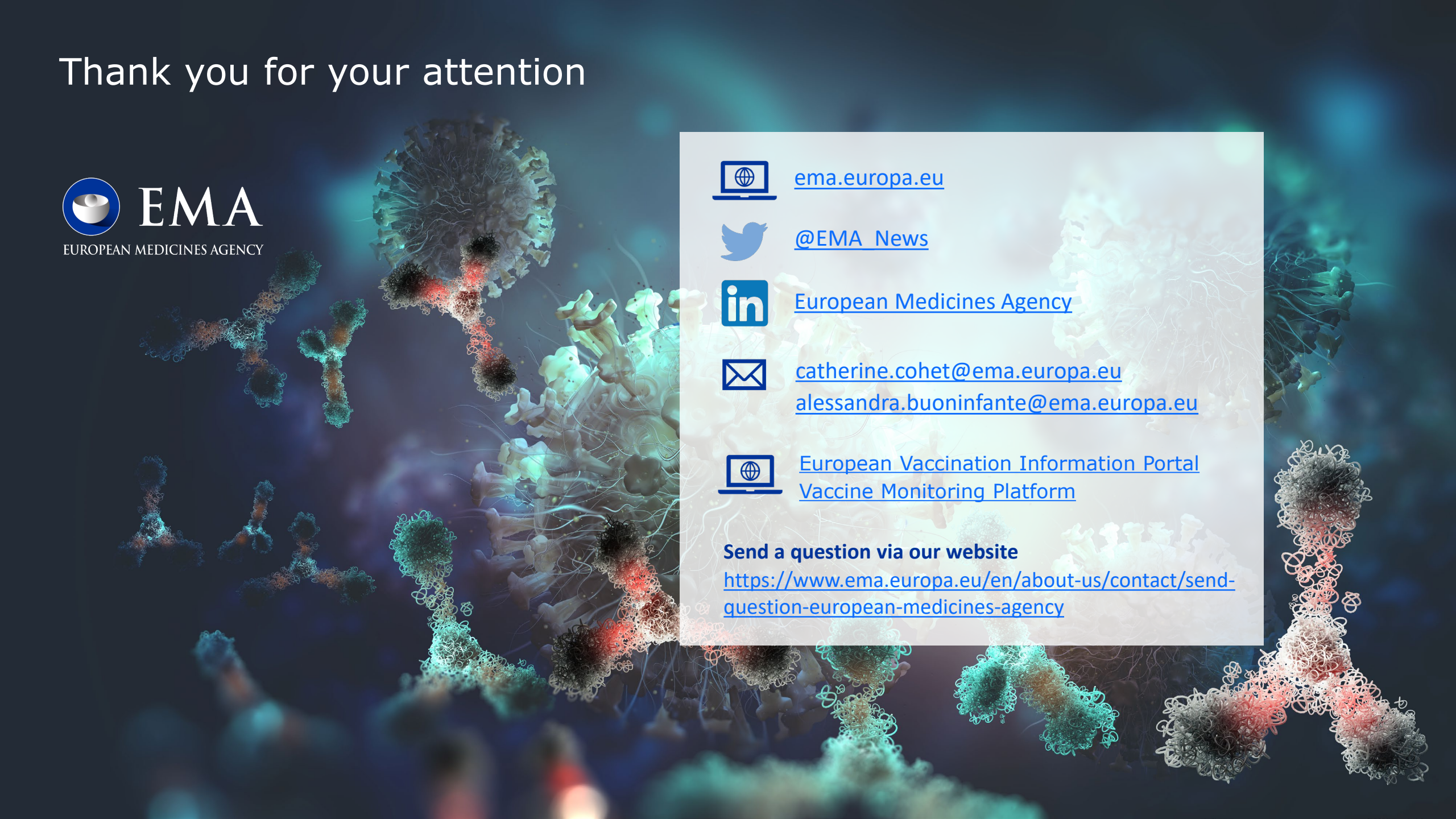
Primary care
COVID-19
Influenza
//
Moderate disease

Key messages

- VMP studies add to the collective **body of evidence** needed by EMA Committees and Working parties, and ETF, to contextualise available evidence on the benefit/risk profile of vaccines
- **Complementary** evidence generation pathways are used by ECDC and EMA to build an agile and evolving vaccine monitoring framework
- Multiple operational and methodological **learnings** from the VMP can benefit pandemic **preparedness** and support the monitoring of licensed vaccines and novel vaccines
- The VMP **communication** plan aims at increasing **transparency** for public health and regulatory stakeholders, patients, HCPs, and the public
- The VMP supports **ETF**, e.g., for recommendations on updates to vaccine composition (e.g., COVID-19, mpox) or for joint recommendations with ECDC on vaccination policy
- Ultimately, evidence generated by the VMP can **inform** patients and HCPs on vaccine safety and effectiveness and support **vaccine confidence**

Thank you for your attention

EMA
EUROPEAN MEDICINES AGENCY



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European Vaccination Information Portal
Vaccine Monitoring Platform

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