LIST OF THE TOPICS INCLUDED IN THE REPORTS ON ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI) AGAINST COVID-19

WASHINGTON, DC

PAHO Pan American Health Organization World Health Organization Americas
In partnership with Canada

List of topics included in weekly reports			
First report	11 February 2021	OFFICIAL REPORTS ON PHARMACOVIGILANCE PROGRAMS	⇨ Argentina ⇨ Canada ⇨ Chile ⇨ Costa Rica ⇨ Mexico ⇨ Spain ⇨ United States
		UPDATES	⇨ Scientists develop COVID-19 nasal vaccines ⇨ Use of vaccines in children and adolescents ⇨ Combined vaccines ⇨ Impact of new SARS-CoV-2 variants
		CLARIFICATIONS/CONCLUSIONS ON EVENTS PRESENTED IN PREVIOUS COMMUNICATIONS	⇨ Cases in Norway ⇨ Sinopharm vaccine trial volunteer in Peru dies of COVID-19-associated pneumonia
		OTHER RELATED UPDATES	⇨ The most common vaccination errors occurring since COVID-19 vaccination began in the United States ⇨ Vaccination of people with COVID-19 infection ⇨ Use of vaccines in older adults ⇨ Authorization of the Pfizer-BioNTech vaccine in 6-dose formulation
Second report	15 February 2021	OFFICIAL REPORTS ON PHARMACOVIGILANCE PROGRAMS	⇨ Argentina ⇨ Brazil ⇨ Canada ⇨ Chile ⇨ Mexico ⇨ Spain ⇨ United States ⇨ VigiBase results ⇨ Safety updates from the European Medicines Agency (EMA) on the Pfizer-BioNTech and Moderna vaccines
		UPDATES	⇨ The CanSino COVID-19 vaccine shows 65.7% effectiveness (02/08) ⇨ Impact of new SARS-CoV-2 Virus variants ⇨ South Africa: SARS-CoV-2 variants ⇨ Bell's Palsy study (facial paralysis) ⇨ Immune thrombocytopenia ⇨ Impact of a vaccine dose on people previously infected with COVID-19
		OTHER RELATED UPDATES	⇨ Moderna and 15 doses ⇨ Japan: The importance of low-dead-space syringes ⇨ Second dose of Moderna and Pfizer vaccines ⇨ Argentina: Update on special situations in the target population to be vaccinated (persons who are pregnant, breastfeeding, immunocompromised, or have autoimmune diseases)

			⇨ COVID-19 vaccine delivery by drone
Third report	24 February 2021	OFFICIAL REPORTS ON PHARMACOVIGILANCE PROGRAMS	⇨ Argentina ⇨ Canada ⇨ Colombia ⇨ Costa Rica ⇨ France ⇨ Mexico
		UPDATES	⇨ Pfizer-BioNTech will begin global clinical trials to evaluate its COVID-19 vaccine in pregnant women ⇨ Spread of SARS-CoV-2 and the Pfizer-BioNTech vaccine ⇨ **Impact of new SARS-CoV-2 variants** ⇨ Evolution of the SARS-CoV-2 virus, impact of circulating variants, and new vaccines ⇨ New strategies to reduce SARS-CoV-2 infection and viral transmission ⇨ The Oxford/AstraZeneca vaccine is more effective with a longer interval between doses
		OTHER RELATED UPDATES	⇨ Problems with incorrect dosage amounts ⇨ Request to change storage conditions ⇨ Inclusion of pregnant and nursing women in COVID-19 vaccine research
Fourth report	4 March 2021	OFFICIAL REPORTS ON PHARMACOVIGILANCE PROGRAMS	⇨ Brazil ⇨ Canada ⇨ Mexico ⇨ United States
		UPDATES	⇨ Effectiveness of the Pfizer-BioNTech Comirnaty mRNA COVID-19 vaccine (with modified nucleosides) ⇨ European research project on SARS-CoV-2 variants and vaccine development ⇨ Study on Effectiveness of first dose of COVID-19 vaccines against hospital admissions in Scotland ⇨ Mass vaccination in the municipality of Serrana, Riberão Preto, Brazil ⇨ Adapting COVID-19 vaccines to SARS-CoV-2 variants: guidance for vaccine manufacturers
		CLARIFICATIONS/CONCLUSIONS ON EVENTS PRESENTED IN PREVIOUS COMMUNICATIONS	⇨ BRAZIL
		OTHER RELATED UPDATES	⇨ Vaccines on the WHO Emergency Use List ⇨ Accidental overdose with COVID-19 vaccine ⇨ Janssen vaccine receives Emergency Use Authorization from the FDA ⇨ Clarifications on indications for use and recommendations for COVID-19 vaccine administration
Fifth report	11 March 2021	OFFICIAL REPORTS ON PHARMACOVIGILANCE PROGRAMS	⇨ Argentina ⇨ Canada ⇨ Costa Rica ⇨ Mexico

			⇨ Updated reports from the European Medicines Agency on the safety of the Pfizer-BioNTech (Comirnaty) and Moderna vaccines
		UPDATES	⇨ AstraZeneca in Canada ⇨ COVID-19 vaccine safety: reports of late local reactions ⇨ Vaccination of people previously infected with the SARS-CoV-2 virus ⇨ SARS-CoV-2 genomic sequencing to improve surveillance ⇨ COVID-19 vaccines authorized in the Region of the Americas, in the country of origin, and by other authorities
		OTHER RELATED UPDATES	⇨ Embarazo y vacuna contra la COVID-19 ⇨ Uso de la vacuna contra la COVID-19 en la Región de las Américas ⇨ Resumen de las características y condiciones de uso de las vacunas utilizadas en la Región
Sixth report	19 March 2021	OFFICIAL REPORTS ON PHARMACOVIGILANCE PROGRAMS	⇨ Brazil ⇨ Canada ⇨ Chile ⇨ France ⇨ Mexico ⇨ Peru ⇨ Spain ⇨ United States
		UPDATES	⇨ Emergency use listing (EUL/WHO): Janssen COVID-19 Vaccine ⇨ Pfizer BioNTech and AstraZeneca Vaccines ⇨ The Finlay Institute (Cuba) moves forward in developing its SARS-CoV-2 vaccine ⇨ Phase III clinical trial with the Sovereign 2 vaccine candidate ⇨ Cellular immune response to COVID-19 and mRNA vaccines
		CLARIFICATIONS/CONCLUSIONS ON EVENTS PRESENTED IN PREVIOUS COMMUNICATIONS	⇨ Update on the AstraZeneca COVID-19 vaccine and thrombosis
		OTHER RELATED UPDATES	⇨ Critical recommendations for vaccine administration ⇨ Preliminary information from a pre-publication (non-peer-reviewed) study: Distribution of reconstituted mRNA vaccines in the United States. ⇨ Destruction of used vials to avoid counterfeiting
Seventh report	22 March 2021	OFFICIAL REPORTS ON PHARMACOVIGILANCE PROGRAMS	⇨ Argentina ⇨ Brazil ⇨ Costa Rica ⇨ Spain ⇨ Mexico ⇨ United Kingdom
		UPDATES	⇨ Development of new vaccines

			⇨ Vaccination and patients with prolonged symptomatology ⇨ Influenza-like illness after administration of COVID-19 vaccines
		OTHER RELATED UPDATES	⇨ Recommendations for countries using AstraZeneca vaccine or adenovirus vaccines in general ⇨ Use of the COVID-19 vaccine in the Region of the Americas as of March 17, 2021
Eighth report	31 March 2021	OFFICIAL REPORTS ON PHARMACOVIGILANCE PROGRAMS	⇨ Canada ⇨ Caribbean Community ⇨ Mexico ⇨ United Kingdom ⇨ United States
		UPDATES	⇨ Possible explanation of rare prothrombotic events with the AstraZeneca vaccine in Europe ⇨ GACVS statement on rare thrombotic events with the AstraZeneca vaccine in Europe ⇨ ANVISA and Butantan discuss anti-SARS-CoV-2 equine serum tests ⇨ New vaccine developments ⇨ Variants and impact on vaccination against COVID-19
		OTHER RELATED UPDATES	⇨ Gavi COVID-19 Vaccines Advance Market Commitment (COVAX AMC) Initiative ⇨ Recommendations for newly vaccinated people ⇨ Traceability and information on COVID-19 vaccines ⇨ Falsified COVID-19 vaccine alert in Mexico
Ninth report	8 April 2021	OFFICIAL REPORTS ON PHARMACOVIGILANCE PROGRAMS	⇨ Argentina ⇨ Canada ⇨ France ⇨ Mexico ⇨ Update on the safety of authorized vaccines: European Medicines Agency
		UPDATES	⇨ COVID-19 vaccination and children ⇨ Pfizer-BioNTech announces positive results for study on COVID-19 vaccine in adolescents
		OTHER RELATED UPDATES	⇨ Evaluation of the effectiveness of the COVID-19 vaccine ⇨ Protection against possible falsification of COVID-19 vaccines ⇨ Use of the COVID-19 vaccine in the Region of the Americas as of 7 April 2021
Tenth report	11 April 2021	OFFICIAL REPORTS ON PHARMACOVIGILANCE PROGRAMS	⇨ Canada ⇨ Costa Rica ⇨ Spain ⇨ United States ⇨ Mexico
		UPDATES	⇨ The number of reported cases of venous thromboembolism associated with the Oxford AstraZeneca vaccine in Denmark is lower than the expected number of cases in the population ⇨ Intranasal COVID-19 vaccine

			⇨ Use of the Janssen (Johnson & Johnson) vaccine has been paused in the United States ⇨ Elevated neutralizing antibody titers and SARS-CoV-2 variants ⇨ Duration of the efficacy of the Pfizer-BioNTech mRNA vaccine
		OTHER RELATED UPDATES	⇨ FDA updates emergency use authorization for Moderna COVID-19 vaccine with respect to the number of available doses per vial ⇨ ANVISA requests modification of Oxford-AstraZeneca-FIOCRUZ vaccine package insert. ⇨ Summary of topics included in the weekly reports (until Ninth Report)
Eleventh report	19 April 2021	OFFICIAL REPORTS ON PHARMACOVIGILANCE PROGRAMS	⇨ Canada ⇨ United States ⇨ Mexico ⇨ Update on the safety of authorized vaccines: European medicines agency
		UPDATES	⇨ Review of rare blood-clotting adverse events with the AstraZeneca COVID-19 vaccine (Vaxzevria and Covishield) by the World Health Organization's Global Advisory Committee on Vaccine Safety ⇨ Use of Janssen vaccine in the United States is temporarily suspended ⇨ The risk of blood clots in the brain due to COVID-19: disease and vaccination. Comments that include information from a non-peer-reviewed study that has not yet been published ⇨ United States reports low rate of new infections in people who have been vaccinated ⇨ Comments on a new SARS-CoV-2 variant of interest detected in Africa, including information from a non-peer-reviewed article not yet published
		OTHER RELATED UPDATES	⇨ Risk of falsified vaccines linked to inadequate disposal of vials ⇨ Use of the COVID-19 vaccine in the Region of the Americas as of 16 April 2021
Ad hoc update	27 April 2021	Ad hoc update to the weekly consolidated information on adverse events following administration of immunization (AEFI) against COVID-19	⇨ Notifications of myocarditis and pericarditis following administration of COVID-19 vaccines ⇨ FDA and CDC pause on the use of Janssen COVID-19 vaccine (updated information) ⇨ Updated WHO Interim recommendations for use of the COVID-19 ChAdOx1-S [recombinant] vaccine (AstraZeneca COVID-19 vaccine AZD1222, SII Covishield, and SK Bioscience) ⇨ Collection of information on recently reported rare and severe events
Twelfth report	5 May 2021	OFFICIAL REPORTS ON PHARMACOVIGILANCE PROGRAMS	⇨ Canada ⇨ Costa Rica ⇨ United States ⇨ France

			⇨ Mexico ⇨ United Kingdom
		UPDATES	⇨ Reports of recommendations from agencies in the Region of the Americas regarding some serious events following administration of COVID-19 vaccines ⇨ ANVISA authorizes FIOCRUZ to produce the active pharmaceutical ingredient (API) for the Oxford-AstraZeneca COVID-19 vaccine ⇨ COVID-19 Variants of concern (VOC)
		OTHER RELATED UPDATES	⇨ New vaccine included in WHO's Emergency Use Listing (EUL) ⇨ International Nonproprietary Names of COVID-19 vaccines ⇨ Use of the COVID-19 vaccine in the Region of the Americas as of 1 May 2021
Thirteenth report	10 May 2021	OFFICIAL REPORTS ON PHARMACOVIGILANCE PROGRAMS	⇨ Canada ⇨ Chile ⇨ Costa Rica ⇨ United States ⇨ Mexico ⇨ United Kingdom
		UPDATES	⇨ PRAC meeting from 3 to 6 May 2021 ⇨ Pfizer-BioNTech COVID-19 vaccine authorization for children 12 to 15 years of age ⇨ ANVISA recommended immediately suspending use of the AstraZeneca/Fiocruz COVID-19 vaccine in pregnant women ⇨ PAHO/WHO COVID-19 resources on vaccination ⇨ Unilateral axillary adenopathy in patients recently vaccinated against COVID-19
		OTHER RELATED UPDATES	⇨ New vaccine included in WHO's Emergency Use Listing ⇨ COVID-19 vaccines involved in incidents of breaks in the cold chain ⇨ Storage temperatures for COVID-19 vaccines
Fourteenth report	20 May 2021	OFFICIAL REPORTS ON PHARMACOVIGILANCE PROGRAMS	⇨ Argentina ⇨ Canada ⇨ Caribbean Community (CARICOM) ⇨ United States ⇨ Mexico ⇨ United Kingdom
		UPDATES	⇨ GACVS Statement on Safety Signals with Johnson & Johnson/Janssen COVID-19 vaccine ⇨ Recommendations on the use of COVID-19 vaccines during pregnancy ⇨ Efficacy of mRNA vaccines against the B.1.617 variant ⇨ Vaccine candidates and platforms in various phases of clinical research as of 14 May 2021 ⇨ Immune response and postponement of second dose of Pfizer COVID-19 vaccine

			⇨ ANVISA conducted research on the number of doses in multidose vials of the CoronaVac vaccine ⇨ Vaccination in Cuba
		OTHER RELATED UPDATES	⇨ International nonproprietary name for the Moderna COVID-19 vaccine
Fifteenth report	2 June 2021	OFFICIAL REPORTS ON PHARMACOVIGILANCE PROGRAMS	⇨ Canada ⇨ Spain ⇨ Italy ⇨ Mexico ⇨ United Kingdom
		UPDATES	⇨ Emergency use listing: Sinovac's COVID-19 vaccine ⇨ Preliminary results on the benefits of combining different COVID-19 vaccines ⇨ Report of the Butantan Institute: Impact of mass vaccination in the municipality of Serrana (preliminary results not yet peer reviewed)
		CLARIFICATIONS/CONCLUSIONS ON EVENTS PRESENTED IN PREVIOUS COMMUNICATIONS	⇨ Information from WHO's GACVS subcommittee regarding reports of cases of myocarditis following administration of mRNA-based COVID-19 vaccines
		OTHER RELATED UPDATES	⇨ The Spanish Agency for Medicines and Medical Devices updates materials on the safety of COVID-19 vaccines ⇨ The European Medicines Agency authorizes the Comirnaty COVID-19 vaccine in children ages 12 to 15 ⇨ FDA authorizes longer time for refrigerator storage of thawed Pfizer-BioNTech COVID19 vaccine prior to dilution ⇨ Naming SARS-CoV-2 variants ⇨ SARS-CoV-2 variants of concern and variants of interest, updated 31 May 2021 ⇨ Use of COVID-19 vaccines in the Region of the Americas as of 30 May 2021
Sixteenth	10 June 2021	OFFICIAL REPORTS ON PHARMACOVIGILANCE PROGRAMS	⇨ Canada ⇨ Hong Kong ⇨ Consolidated information on AEFI, serious AEFI, and deaths following administration of COVID-19 vaccines administered in the Region of the Americas
		UPDATES	⇨ COVID-19 Vaccine Pharmacovigilance Dashboard ⇨ Study on effectiveness of vaccination against SARS-CoV-2 in Uruguay in 2021: preliminary results ⇨ Effectiveness of a single dose of Sputnik V COVID-19 vaccine (not yet peer reviewed) ⇨ ANVISA authorizes clinical studies of the ButanVac vaccine
		CLARIFICATIONS/CONCLUSIONS ON EVENTS PRESENTED IN PREVIOUS COMMUNICATIONS	⇨ Brighton Collaboration updates interim case definition of thrombosis and thrombocytopenia syndrome
		OTHER RELATED UPDATES	⇨ Best practices in using the decisions of regulatory authorities from other jurisdictions in regulating medical products

			⇨ Technology transfer of the mRNA-based COVID-19 vaccine ⇨ Authorization of Pfizer-BioNTech's Comirnaty vaccine in the 12- to 16-yearold age group ⇨ Recommendations of the European Centre for Disease Prevention and Control on vaccinating adolescents against COVID-19 ⇨ Global BioHub for pathogen storage, sharing, and analysis
Seventeenth report	17 June 2021	OFFICIAL REPORTS ON PHARMACOVIGILANCE PROGRAMS	⇨ Canada ⇨ Spain ⇨ Switzerland
		UPDATES	⇨ Update on SARS-CoV-2 variants of concern ⇨ Results of clinical studies of the Novavax vaccine show that it is safe and prevents COVID-19 ⇨ Progress in clinical trials of COVID-19 vaccines in Cuba ⇨ ANVISA authorizes exceptional import of Sputnik V to Brazilian states
		CLARIFICATIONS/CONCLUSIONS ON EVENTS PRESENTED IN PREVIOUS COMMUNICATIONS	⇨ Updated SAGE/WHO recommendations for use of the Pfizer-BioNTech, Moderna, and Janssen COVID-19 vaccines ⇨ The European Medicines Agency (EMA) includes capillary leak syndrome as a contraindication for the Vaxzevria vaccine
		OTHER RELATED UPDATES	⇨ FDA authorizes an extension of the shelf-life of Pfizer-BioNTech COVID-19 vaccine under refrigeration ⇨ Chile's Institute of Public Health authorizes an update to the refrigerator storage period for the Pfizer-BioNTech vaccine ⇨ Chile's Institute of Public Health Authorizes Emergency Use of Janssen's COVID-19 Vaccine through the COVAX Mechanism
Eighteenth report	30 June 2021	OFFICIAL REPORTS ON PHARMACOVIGILANCE PROGRAMS	⇨ Canada ⇨ Costa Rica ⇨ United States ⇨ Paraguay
		UPDATES	⇨ Possibility of contracting COVID-19 after being vaccinated ⇨ Report from England notes that the Pfizer-BioNTech and Oxford-AstraZeneca vaccines are highly effective in preventing hospitalizations from infection by the Delta variant of COVID-19
		OTHER RELATED UPDATES	⇨ Commercial name for the Moderna COVID-19 vaccine ⇨ Guillain-Barré syndrome (GBS) and AstraZeneca's COVID-19 vaccine ⇨ Bell's palsy in cases of post-vaccination COVID-19 infection ⇨ Use of the COVID-19 vaccine in the Region of the Americas as of 24 June 2021

Nineteenth report	12 July 2021	OFFICIAL REPORTS ON PHARMACOVIGILANCE PROGRAMS	⇨ Argentina ⇨ Canada ⇨ Paraguay ⇨ AEFI and serious adverse events reported for vaccines being used in the Region of the Americas, by doses administered, as of 30 June 2021
		UPDATES	⇨ Update on SARS-CoV-2 variants of interest ⇨ CECMED grants emergency use authorization (EUA) to the Cuban vaccine candidate Abdala ⇨ Preliminary results of the CombiVacS study conducted in Spain
		CLARIFICATIONS/CONCLUSIONS ON EVENTS PRESENTED IN PREVIOUS COMMUNICATIONS	⇨ Warning about possible risk of myocarditis/pericarditis with mRNA vaccines ⇨ The European Medicines Agency adds capillary leak syndrome as a contraindication to Janssen's COVID-19 vaccine
		OTHER RELATED UPDATES	⇨ European Medicines Agency guidance for variant strain(s) update to COVID-19 vaccines ⇨ WHO EUL recommendation for BIBP's COVID-19 vaccine risk management plan and vaccine pharmacovigilance ⇨ COVID-19 vaccine traceability initiative
Twenty report	21 July 2021	OFFICIAL REPORTS ON PHARMACOVIGILANCE PROGRAMS	⇨ Argentina ⇨ Canada ⇨ United States
		UPDATES	⇨ WHO SAGE Roadmap for Prioritizing Use of COVID-19 Vaccines in the Context of Limited Supply ⇨ Brazil's National Health Surveillance Agency Authorizes Clinical Trial for AstraZeneca's Modified Vaccine
		CLARIFICATIONS/CONCLUSIONS ON EVENTS PRESENTED IN PREVIOUS COMMUNICATIONS	⇨ Guidance for clinical case management of thrombosis with thrombocytopenia syndrome related to administration of COVID-19 vaccines ⇨ Warning about possible risk of Guillain-Barré Syndrome with viral vector COVID-19 vaccines
		OTHER RELATED UPDATES	⇨ Recommendation of WHO/EUL on risk management plan and pharmacovigilance plan for Sinovac COVID-19 vaccine
Tweenty-first report	29 July 2021	OFFICIAL REPORTS ON PHARMACOVIGILANCE PROGRAMS	⇨ Canada ⇨ Chile ⇨ Costa Rica
		UPDATES	⇨ The European Medicines Agency authorizes use of the Spikevax COVID-19 vaccine for children ages 12 to 17 ⇨ Updated Brighton Collaboration case definition of myocarditis/pericarditis ⇨ Effectiveness of an inactivated SARS-CoV-2 vaccine in Chile
		CLARIFICATIONS/CONCLUSIONS ON EVENTS PRESENTED IN PREVIOUS COMMUNICATIONS	⇨ Warning about possible risk of Guillain-Barré Syndrome with viral vector COVID-19 vaccines
		OTHER RELATED UPDATES	⇨ Inclusions in the WHO Emergency Use Listing (EUL)

			⇨ Adverse Events of Special Interest (AESI) and related risks ⇨ Alert on the need for sufficient syringes for vaccination
Twenty-second report	13 August 2021	OFFICIAL REPORTS ON PHARMACOVIGILANCE PROGRAMS	⇨ CANADA ⇨ UNITED STATES (data as of 11 August) ⇨ UNITED KINGDOM (data as of 11 August)
		UPDATES	⇨ Heterologous COVID-19 vaccination strategy ⇨ Brazil's National Health Surveillance Agency issues alert on rare cases of post-vaccination Guillain-Barré Syndrome ⇨ U.S. Food and Drug Administration Authorizes Extending the Shelf-life of Janssen's COVID-19 Vaccine ⇨ Reports of menstrual disorders and unexpected vaginal bleeding following administration of COVID-19 vaccines of Pfizer-BioNTech, Moderna, and AstraZeneca ⇨ U.S. Food and Drug Administration (FDA) authorizes export of batches of the active ingredient in AstraZeneca's COVID-19 vaccine
		CLARIFICATIONS/CONCLUSIONS ON EVENTS PRESENTED IN PREVIOUS COMMUNICATIONS	⇨ Updated recommendations by the WHO Strategic Advisory Group of Experts on the use of ChAdOx1-S-based (recombinant) COVID-19 vaccines ⇨ Preliminary recommendations of the WHO Strategic Advisory Group of Experts on heterologous immunization schemes, fractional doses, and booster doses of COVID-19 vaccines
		OTHER RELATED UPDATES	⇨ Allergic reactions after vaccination with COVID-19 vaccines ⇨ WHO alert on falsified Covishield COVID-19 vaccine ⇨ Adverse Events of Special Interest (AESI) and related risks: facial palsy/Bell's palsy/peripheral facial nerve palsy
Twenty-third report	23 August 2021	OFFICIAL REPORTS ON PHARMACOVIGILANCE PROGRAMS	⇨ CANADA ⇨ URUGUAY ⇨ Consolidated number of reported adverse events and reporting rate (reports per 100,000 doses administered), by vaccine, for countries in the Americas that reported to the UMC or publicly as of 31 July 2021
		UPDATES	⇨ FDA Approves First COVID-19 Vaccine ⇨ Joint Statement from Health and Human Services (HHS) Public Health and Medical Experts on COVID-19 Booster Shots ⇨ CECMED grants emergency use authorization to the Soberana 02 and Soberana Plus vaccines ⇨ Immune Response to Sinovac-CoronaVac Vaccine ⇨ Small study in Singapore appears to show that COVID-19 vaccines induce potent immune response in people who had been infected with the SARS virus

			⇨ India's National Regulatory Authority Authorizes First DNA COVID-19 Vaccine
		CLARIFICATIONS/CONCLUSIONS ON EVENTS PRESENTED IN PREVIOUS COMMUNICATIONS	⇨ Interim Statement on COVID-19 Vaccine Booster Doses (WHO/SAGE), 10 August 2021
		OTHER RELATED UPDATES	⇨ Alert by the Public Health Institute of Chile on suspension of a lot of the CanSino COVID-19 vaccine ⇨ Additions to the WHO Emergency Use Listing (EUL) ⇨ Adverse Events of Special Interest (AESI) and related risks: Thrombosis with thromboembolism syndrome (TTS)
Twenty-fourth report	6 September 2021	OFFICIAL REPORTS ON PHARMACOVIGILANCE PROGRAMS	⇨ ARGENTINA ⇨ CANADA
		UPDATES	⇨ New COVID-19 variant of interest, named “Mu” ⇨ Israeli Study on safety of the Pfizer-BioNTech BNT162b2 mRNA COVID-19 vaccine ⇨ ANVISA requests information from Pfizer-BioNTech, Janssen, and Butantan on booster doses of their respective vaccines ⇨ Resurgence of SARS-CoV-2 Infection in a Highly Vaccinated Health System Workforce ⇨ Bell's palsy following vaccination with Pfizer-BioNTech mRNA and inactivated (CoronaVac) SARS-CoV-2 vaccine ⇨ Cutaneous and hypersensitivity reactions associated with COVID-19 vaccination – a narrative review ⇨ Nervous and muscular adverse events after COVID-19 vaccination: a systematic review and meta-analysis of clinical trials ⇨ Cardiovascular Adverse Events Reported from COVID-19 Vaccines: A Study Based on WHO Database
		CLARIFICATIONS/CONCLUSIONS ON EVENTS PRESENTED IN PREVIOUS COMMUNICATIONS	⇨ The European Medicines Agency reviews cases of multisystem inflammatory syndrome ⇨ Update on SARS-CoV-2 Variants of Concern
		OTHER RELATED UPDATES	⇨ Chile's Institute of Public Health Expands CoronaVac Vaccine Age Group to Include Children Age 6 and Older ⇨ Update to the Alert on Falsified Covishield COVID-19 vaccine
Twenty-fifth report	20 September 2021	OFFICIAL REPORTS ON PHARMACOVIGILANCE PROGRAMS	⇨ Doses administered, spontaneous reports of suspected cases of AEFI, and fatal outcomes in Europe, based on the EudraVigilance database as of 2 September 2021 ⇨ BRAZIL ⇨ CANADA ⇨ UNITED STATES (data to 8 September) ⇨ URUGUAY
		UPDATES	⇨ WHO calls for moratorium on the use of COVID-19 vaccine booster doses

			⇨ Surveillance of adverse events following administration of COVID-19 mRNA vaccines ⇨ Risk factors and disease profile of post-vaccination SARS-CoV-2 infection in UK users of the COVID Symptom Study app ⇨ Study on allergic reactions after administration of the Pfizer-BioNTech COVID-19 vaccine among adults with high allergy risk
		CLARIFICATIONS/CONCLUSIONS ON EVENTS PRESENTED IN PREVIOUS COMMUNICATIONS	⇨ The European Agency for Medicines and Medical Products updates information on the safety of COVID-19 vaccines
		OTHER RELATED UPDATES	⇨ Brazilian Ministry of Health issues technical note on booster doses of COVID-19 vaccines
Twenty-sixth report	27 September 2021	OFFICIAL REPORTS ON PHARMACOVIGILANCE PROGRAMS	⇨ CANADA ⇨ COLOMBIA ⇨ UNITED STATES (data to 22 September) ⇨ PANAMA
		UPDATES	⇨ U.S. Food and Drug Administration authorizes a booster dose of the Pfizer-BioNTech COVID-19 vaccine for certain populations ⇨ CDC Statement on recommendation of the Advisory Committee on Immunization Practices (ACIP) ⇨ Colombia's National Institute for Drug and Food Surveillance (INVIMA) approves administration of Moderna's COVID-19 vaccine for people ages 12 to 17 ⇨ Study on the risk of SARS-CoV-2 infection and subsequent hospital admission and death at different time intervals since the first dose of COVID-19 vaccine administration ⇨ Maternal and child outcomes reported by breastfeeding women following administration of messenger RNA COVID-19 vaccination
		CLARIFICATIONS/CONCLUSIONS ON EVENTS PRESENTED IN PREVIOUS COMMUNICATIONS	⇨ WHO authorizes extension of the shelf-life of Pfizer-BioNTech's Comirnaty vaccine ⇨ WHO authorizes new production site for Pfizer-BioNTech's Comirnaty vaccine ⇨ Chile's Institute of Public Health issues an information notice on the safety of Pfizer-BioNTech's COVID-19 vaccine following reports of myocarditis and pericarditis
		OTHER RELATED UPDATES	⇨ Selection of two regional centers for the development and production of mRNA vaccines in Latin America ⇨ The National Institute of Drug and Food Surveillance (INVIMA) participates in “Solidarity Trial of COVID-19 vaccine candidates”
Twenty-seventh report	4 October 2021	OFFICIAL REPORTS ON PHARMACOVIGILANCE PROGRAMS	⇨ CANADA ⇨ CARIBBEAN PUBLIC HEALTH AGENCY (CARPHA) ⇨ COVID-19 vaccination for pregnant women, and pregnancy outcomes

			⇨ Declining mortality from cerebral venous sinus thrombosis with thrombocytopenia (CVST) after SARS-CoV-2 vaccination ⇨ Cerebral venous thrombosis after vaccination against COVID-19 in the UK: a multicenter cohort study ⇨ Myocarditis and pericarditis after vaccination for COVID-19
		UPDATES	⇨ Update to the WHO interim statement of the Strategic Advisory Group of Experts on Immunization regarding booster doses for COVID-19 vaccination ⇨ Meeting highlights from the Pharmacovigilance Risk Assessment Committee of the European Medicines Agency, from 27 to 30 September 2021
		CLARIFICATIONS/CONCLUSIONS ON EVENTS PRESENTED IN PREVIOUS COMMUNICATIONS	⇨ Safety and efficacy of the NVX-CoV2373 COVID-19 vaccine
		OTHER RELATED UPDATES	⇨ Co-administration of COVID-19 vaccines with other vaccines ⇨ United States: Studies are being planned and conducted to evaluate the safety and immunogenicity of co-administering COVID-19 vaccines with other vaccines. Extensive research on the simultaneous administration of the most widely used live and inactivated vaccines has demonstrated seroconversion rates and rates for adverse reactions similar to those observed when the vaccines are administered separately. ⇨ Booster doses of Janssen's and Moderna's COVID-19 Vaccines: Meeting of the U.S. Food and Drug Administration (FDA) Vaccines and Related Biological Products Advisory Committee ⇨ Adverse Events of Special Interest (AESI) and Related Risks: Multisystem Inflammatory Syndrome in Children
Twenty-eighth report	22 October 2021	OFFICIAL REPORTS ON PHARMACOVIGILANCE PROGRAMS	⇨ CANADA ⇨ CHILE ⇨ UNITED STATES ⇨ MEXICO ⇨ Publications on potential safety signals identified with the use of COVID-19 vaccines
		UPDATES	⇨ Inclusions in the WHO Emergency Use Listing (EUL) ⇨ U.S. Food and Drug Administration authorizes a booster dose of the COVID-19 vaccines of Moderna, Janssen, and Pfizer-BioNTech for certain at-risk populations ⇨ EMA ends rolling review of CVnCoV COVID-19 vaccine following withdrawal by CureVac AG
		CLARIFICATIONS/CONCLUSIONS ON EVENTS PRESENTED IN PREVIOUS COMMUNICATIONS	⇨ Recommendations of the WHO Strategic Advisory Group of Experts (SAGE) on Immunization regarding WHO/EUL COVID-19 vaccines
		OTHER RELATED UPDATES	⇨ Mix-ups between the influenza (flu) vaccine and COVID-19 vaccines

			⇨ Adverse Events of Special Interest (AESI) and Related Risks: Thrombocytopenia
Twenty-ninth report	29 October 2021	OFFICIAL REPORTS ON PHARMACOVIGILANCE PROGRAMS	⇨ ARGENTINA ⇨ COSTA RICA ⇨ PARAGUAY ⇨ Consolidated adverse events reported by countries of the Region, by vaccine, September 2021 ⇨ Publications on potential safety signals identified with the use of COVID-19 vaccines
		UPDATES	⇨ European Medicines Agency (EMA) authorizes ready-to-use formulation of Pfizer-BioNTech COVID-19 vaccine 8 ⇨ U.S. Food and Drug Administration Authorizes Change to Pfizer-BioNTech Vaccine Formulation ⇨ Update from the U.S. Centers for Disease Control and Prevention on Interim Clinical Considerations for the Use of COVID-19 Vaccines in Specific Populations ⇨ Emergency Use Authorization (EUA) of the Pfizer-BioNTech COVID-19 vaccine to include children ages 5 to 11
		CLARIFICATIONS/CONCLUSIONS ON EVENTS PRESENTED IN PREVIOUS COMMUNICATIONS	⇨ Update on recommendations of the WHO Strategic Advisory Committee of Experts (SAGE) on Immunization for the use of Sinovac and Sinopharm COVID-19 vaccines ⇨ Incorporation of conservation and use guidelines to the pharmacovigilance dashboard of COVID-19 vaccines
		OTHER RELATED UPDATES	⇨ Interim Recommendations by the U.S. Centers for Disease Control and Prevention on COVID-19 Vaccine Administration Errors and Deviations ⇨ Delta subvariant of the novel Coronavirus has been circulating with increasing intensity in Belém, Pará ⇨ Adverse Events of Special Interest (AESI) and Related Risks: Acute myelitis
Thirtieth report	8 November 2021	OFFICIAL REPORTS ON PHARMACOVIGILANCE PROGRAMS	⇨ BRAZIL (State of Rio Grande do Sul) ⇨ CANADA ⇨ COLOMBIA ⇨ UNITED STATES ⇨ PARAGUAY ⇨ Publications on potential safety signals identified with the use of COVID-19 vaccines
		UPDATES	⇨ Inclusion of an additional vaccine on the WHO Emergency Use Listing (EUL) ⇨ WHO Interim Recommendation for Use of the Bharat Biotech COVAXIN vaccine against COVID-19 ⇨ AEFI reported to Chile's National Center for Pharmacovigilance (CNFV) since the start of the vaccination campaign in the six-to-eleven-year-old age group with inactivated SARS-CoV-2 vaccine (CoronaVac)
		CLARIFICATIONS/CONCLUSIONS ON EVENTS PRESENTED IN PREVIOUS COMMUNICATIONS	⇨ There are no additional updates to the most recent bulletin on conclusive analyses of AEFI

		OTHER RELATED UPDATES	⇨ WHO alert on falsified Pfizer-BioNTech COVID-19 vaccine ⇨ Considerations on the falsified vaccines ⇨ Adverse Events of Special Interest (AESI) and related risks: Vaccine-associated enhanced disease (VAED)
Thirty-first report	20 December 2021	OFFICIAL REPORTS ON PHARMACOVIGILANCE PROGRAMS	⇨ ARGENTINA (Special report on vaccine safety surveillance in children and adolescents) ⇨ CANADA ⇨ MEXICO ⇨ PARAGUAY ⇨ Consolidated reports of adverse events, by vaccine, in countries of the Region of the Americas, December 2021 ⇨ Publications on potential signs of problems with the safety of COVID-19 vaccines ⇨ A systematic review of cases of central nervous system (CNS) demyelination following COVID-19 vaccination ⇨ Immunogenicity and Risk of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Infection after Coronavirus Disease 2019 (COVID-19) vaccination in patients with cancer: a systematic review and meta-analysis ⇨ Association between vaccination with the BNT162b2 mRNA COVID-19 vaccine and Bell's palsy: a population-based study ⇨ Thrombotic Events after COVID-19 Vaccination in the Over-50s: Results from a Population-Based Study in Italy ⇨ Risk-benefit analysis of the AstraZeneca COVID-19 vaccine in Australia using a Bayesian network modelling framework
		UPDATES	⇨ HO Adds Pfizer-BioNTech COVID-19 Vaccine Ready-to-Use Formulation to Emergency Use Authorization ⇨ The Committee for Medicinal Products for Human Use (CHMP), of the European Medicines Agency, recommends authorization of the Pfizer-BioNTech Comirnaty vaccine in children ages 5 to 11 years ⇨ EMA and ECDC recommendations on heterologous vaccination courses against COVID-19 ⇨ Update on the risk of myocarditis and pericarditis with COVID-19 mRNA vaccines ⇨ The U.S. Food and Drug Administration Expands Eligibility for Pfizer-BioNTech COVID-19 Booster Dose to 16- and 17-Year-olds
		CLARIFICATIONS/CONCLUSIONS ON EVENTS PRESENTED IN PREVIOUS COMMUNICATIONS	⇨ SAGE/WHO interim statement on COVID-19 vaccination for children and adolescents ⇨ Update on SAGE/WHO recommendations for the use of the Janssen COVID-19 vaccine ⇨ Recommendations of the WHO Strategic Advisory Group of Experts on Immunization on heterologous schedules

		OTHER RELATED UPDATES	⇨ Inclusions in the WHO Emergency Use Listing (EUL) ⇨ For more information on these vaccines, visit: https://extranet.who.int/pqweb/vaccines/vaccinescovid-19-vaccine-eul-issued ⇨ Update to PAHO's COVID-19 Vaccine Pharmacovigilance Dashboard ⇨ Decisions of the Region's Regulatory Authorities
Thirty-second report	30 January 2022	OFFICIAL REPORTS ON PHARMACOVIGILANCE PROGRAMS	⇨ CANADA ⇨ UNITED STATES ⇨ Consolidated adverse events of special interest (AESI) reported by countries in the Region, by vaccine, December 2021 ⇨ Publications on potential safety signals identified in the use of COVID-19 vaccines ⇨ RECOVAC Immune-response Study: The Immunogenicity, Tolerability, and Safety of COVID-19 Vaccination in Patients with Chronic Kidney Disease, on Dialysis, or Living with a Kidney Transplant ⇨ Immune thrombocytopenia following immunization with Vaxzevria ChadOx1-S (AstraZeneca) vaccine, Victoria, Australia ⇨ Risks of myocarditis, pericarditis, and cardiac arrhythmias associated with COVID-19 vaccination or SARS-CoV-2 infection ⇨ Incidence of Myopericarditis and Myocardial Injury in Coronavirus Disease 2019 Vaccinated Subjects ⇨ Risk of venous thrombotic events and thrombocytopenia in sequential time periods after ChAdOx1 and BNT162b2 COVID-19 vaccines: A national cohort study in England ⇨ SARS-CoV-2 infection and COVID-19 vaccination rates in pregnant women in Scotland
		UPDATES	⇨ The European Medicines Agency recommends Nuvaxovid for authorization in the EU ⇨ Meeting highlights from the Pharmacovigilance Risk Assessment Committee of the European Medicines Agency ⇨ The U.S. Food and Drug Administration authorizes a second Moderna COVID-19 vaccine, Spikevax, for marketing in the United States
		CLARIFICATIONS/CONCLUSIONS ON EVENTS PRESENTED IN PREVIOUS COMMUNICATIONS	⇨ Update to the WHO interim statement of the Strategic Advisory Group of Experts on Immunization regarding booster doses for COVID-19 vaccination ⇨ Interim Statement on COVID-19 vaccines in the context of the circulation of the Omicron SARS-CoV-2 Variant of Concern (VOC) from the WHO Technical Advisory Group ⇨ The European Medicines Agency notes that COVID-19 vaccines remain effective against severe disease and hospitalizations caused by the Omicron variant

			⇨ According to the European Medicines Agency, the latest safety data provide reassurance about the use of mRNA COVID-19 vaccines during pregnancy
		OTHER RELATED UPDATES	⇨ Decisions of the Region's Regulatory Authorities
Thirty- third report	28 February 2022	OFFICIAL REPORTS ON PHARMACOVIGILANCE PROGRAMS	⇨ BRAZIL ⇨ CANADA ⇨ ENGLISH-SPEAKING CARIBBEAN ⇨ COLOMBIA ⇨ UNITED STATES ⇨ PARAGUAY ⇨ Publications on potential safety signals identified with the use of COVID-19 vaccines ⇨ Final efficacy analysis, interim safety analysis, and immunogenicity of a single dose of recombinant novel coronavirus vaccine (adenovirus type 5 vector) in adults 18 years and older: an international, multicenter, randomized, double-blinded, placebo-controlled phase 3 trial ⇨ SARS-CoV-2 vaccination and myocarditis or myopericarditis: population-based cohort study ⇨ Myocardial infarction, stroke, and pulmonary embolism after BNT162b2 mRNA COVID-19 vaccine in people aged 75 years or older, in France ⇨ Cases of myocarditis reported after mRNA-based COVID-19 vaccination in the U.S. from December 2020 to August 2021 ⇨ Myocarditis after COVID-19 vaccination in a large health care organization in Israel ⇨ Evaluation of the safety, immunogenicity, and efficacy of SARS-CoV-2 mRNA-1273 vaccine in adolescents ⇨ Safety and immunogenicity of seven COVID-19 vaccines as a third dose (booster) following two doses of ChAdOx1 nCov-19 or BNT162b2 in the UK (COV-BOOST): a blinded, multicenter, randomized, controlled, phase 2 trial
		UPDATES	⇨ COVID-19 vaccines safety update, for vaccines authorized by the European Medicines Agency ⇨ Report on the Global Regulatory Response to the Omicron Variant from the International Coalition of Medicines Regulatory Authorities (ICMRA) ⇨ COVID-19 vaccines and their use in children, pregnant women, and immunocompromised individuals
		CLARIFICATIONS/CONCLUSIONS ON EVENTS PRESENTED IN PREVIOUS COMMUNICATIONS	⇨ Updated recommendations of the WHO Strategic Advisory Committee of Experts (SAGE) on Immunization for the Pfizer-BioNTech mRNA COVID-19 vaccine ⇨ Updated recommendations of the WHO Strategic Advisory Committee of Experts (SAGE) on Immunization for the Moderna mRNA COVID-19 vaccine

			⇨ The EMA Pharmacovigilance Risk Assessment Committee assessed reported cases of menstrual disorders with COVID-19 mRNA vaccines
		OTHER RELATED UPDATES	⇨ WHO authorizes shelf-life extension of Moderna's COVID-19 mRNA vaccine ⇨ Self-study course on the WHO methodology for AEFI causality assessment ⇨ The European Medicines Agency updates the guidance for preparing risk management plans for COVID-19 vaccines ⇨ Decisions of the Region's Regulatory Authorities ⇨ Health Canada, Canada ⇨ Administration errors in Uruguay
Thirty-fourth report	30 March 2022	OFFICIAL REPORTS ON PHARMACOVIGILANCE PROGRAMS	⇨ CANADA ⇨ ENGLISH-SPEAKING CARIBBEAN ⇨ CHILE ⇨ COLOMBIA ⇨ UNITED STATES ⇨ PARAGUAY ⇨ Publications on potential safety signals identified in the use of COVID-19 vaccines ⇨ Risk of Second Allergic Reaction to SARS-CoV-2 Vaccines: A Systematic Review and Meta-analysis ⇨ Association of AZD1222 and BNT162b2 COVID-19 Vaccination with Thromboembolic and Thrombocytopenic Events in Frontline Personnel. A Retrospective Cohort Study ⇨ Final Analysis of Efficacy and Safety of Single-dose Ad26.COV2.S ⇨ Heterologous versus homologous COVID-19 booster vaccination in previous recipients of two doses of CoronaVac COVID-19 vaccine in Brazil (RHH-001): a phase 4, non-inferiority, single blind, randomized study ⇨ Association Between the BNT162b2 Messenger RNA COVID-19 Vaccine and the Risk of Sudden Sensorineural Hearing Loss ⇨ Safety of Inactivated and mRNA COVID-19 Vaccination among Patients Treated for Hypothyroidism: A population-Based Cohort Study ⇨ Thrombotic events following COVID-19 vaccines compared to influenza vaccines
		UPDATES	⇨ Recommendations of the European Medicines Agency's Committee for Medicinal Products for Human Use ⇨ Recommendations of the Pharmacovigilance Risk Assessment Committee of the European Medicines Agency, and safety updates for COVID-19 vaccines
		CLARIFICATIONS/CONCLUSIONS ON EVENTS PRESENTED IN PREVIOUS COMMUNICATIONS	⇨ Interim Statement on COVID-19 vaccines in the context of the circulation of the Omicron SARS-CoV-2 Variant from the WHO Technical Advisory Group on COVID-19 Vaccine Composition

			⇨ Suspension of supply of Bharat Biotech's Covaxin COVID-19 vaccine, through UN procurement agencies ⇨ Updated recommendations of WHO's Strategic Advisory Group of Experts (SAGE) on Immunization for Bharat Biotech, Sinopharm, Sinovac, and AstraZeneca/SII vaccines
		OTHER RELATED UPDATES	⇨ Extension of Refrigerated Shelf Life of Janssen's COVID-19 Vaccine ⇨ WHO Virtual Course on Vaccine Safety Basics ⇨ Decisions of the Region's Regulatory Authorities
Thirty-fifth report	30 April 2022	OFFICIAL REPORTS ON PHARMACOVIGILANCE PROGRAMS	⇨ ARGENTINA ⇨ CANADA ⇨ ENGLISH-SPEAKING CARIBBEAN ⇨ ECUADOR ⇨ UNITED STATES ⇨ PARAGUAY
		UPDATES	⇨ Joint statement by the European Center for Disease Prevention and Control and the European Medicines Agency on the administration of a fourth dose of COVID-19 mRNA vaccines
		CLARIFICATIONS/CONCLUSIONS ON EVENTS PRESENTED IN PREVIOUS COMMUNICATIONS	⇨ Meeting highlights from the European Medicines Agency's Pharmacovigilance Risk Assessment Committee (PRAC) meeting of 4-7 April 2022 ⇨ Plenary meeting of the WHO Strategic Advisory Group of Experts (SAGE) on Immunization
		OTHER RELATED UPDATES	⇨ WHO recommends the use of nirmatrelvir and ritonavir in patients with mild to moderate COVID-19 at high risk of hospitalization ⇨ Decisions of the Region's Regulatory Authorities ⇨ Chile's Public Health Institute authorizes use of the Moderna vaccine in children between the ages of 6 and 11
Thirty-sixth report	31 May 2022	OFFICIAL REPORTS ON PHARMACOVIGILANCE PROGRAMS	⇨ CANADA ⇨ ENGLISH-SPEAKING CARIBBEAN ⇨ COLOMBIA ⇨ UNITED STATES ⇨ PARAGUAY ⇨ PERU ⇨ MEXICO ⇨ Publications on potential safety signals identified with the use of COVID-19 vaccines ⇨ Efficacy and Safety of a Recombinant Plant-Based Adjuvanted COVID-19 Vaccine: CoVLP+AS03 ⇨ Safety, immunogenicity and reactogenicity of the COVID-19 vaccines BNT162b2 and mRNA-1273 administered as fourth-dose boosters after two doses of ChAdOx1 nCoV-19 or BNT162b2 and a third dose of BNT162b2 (VOC-BOOST)

			⇨ Association of Prior BNT162b2 COVID-19 Vaccination with Symptomatic SARS-CoV-2 Infection in Children and Adolescents During Omicron Predominance ⇨ Protection and waning of natural and hybrid immunity to SARS-CoV-2
		UPDATES	⇨ U.S. Food and Drug Administration (FDA) Pfizer-BioNTech COVID-19 vaccine authorization for children 12 to 15 years of age
		CLARIFICATIONS/CONCLUSIONS ON EVENTS PRESENTED IN PREVIOUS COMMUNICATIONS	⇨ Interim statement on the use of additional booster doses of Emergency Use Listed mRNA vaccines against COVID-19 ⇨ U.S. Food and Drug Administration authorizes a booster dose of the Pfizer-BioNTech COVID-19 vaccine for certain populations
		OTHER RELATED UPDATES	⇨ Inclusions in the WHO Emergency Use Listing (EUL) ⇨ Decisions of Regulatory Authorities in the Region
Thirty-seventh report	7 July 2022	OFFICIAL REPORTS ON PHARMACOVIGILANCE PROGRAMS	⇨ ARGENTINA ⇨ CANADA ⇨ UNITED STATES ⇨ Publications on potential safety signals identified in the use of COVID-19 vaccines ⇨ Efficacy and safety of the RBD-dimer-based COVID-19 vaccine ZF2001 in adults ⇨ Safety and immunogenicity of the FINLAY-FR-1A vaccine in COVID-19 convalescent participants: an open-label phase 2a and double-blind, randomized, placebo-controlled, phase 2b, seamless, clinical trial ⇨ Change in COVID-19 risk over time following vaccination with CoronaVac: test negative case-control study ⇨ Analysis of Postvaccination Breakthrough COVID-19 Infections Among Adults with HIV in the United States
		UPDATES	⇨ European Medicines Agency recommends authorization of Nuvaxovid COVID-19 vaccine for adolescents ages 12 to 17 ⇨ European Medicines Agency recommends authorization of Valneva's COVID-19 vaccine
		CLARIFICATIONS/CONCLUSIONS ON EVENTS PRESENTED IN PREVIOUS COMMUNICATIONS	⇨ Interim statement of the WHO Strategic Advisory Group of Experts on Immunization on hybrid immunity and increasing population seroprevalence rates ⇨ Interim statement by the WHO Strategic Advisory Group of Experts on Immunization on decision-making considerations for the use of updated COVID-19 vaccines adapted to COVID-19 variants ⇨ Interim recommendations of the WHO Strategic Advisory Committee of Experts (SAGE) on Immunization for the use of the Janssen COVID-19 vaccine
		OTHER RELATED UPDATES	⇨ The EMA publishes a new version of guidance for variant strains update to COVID-19 vaccines

			⇨ Decisions of Regional Regulatory Authorities
Thirty-eighth report	12 September 2022	OFFICIAL REPORTS ON PHARMACOVIGILANCE PROGRAMS	⇨ BRAZIL ⇨ CANADA ⇨ UNITED STATES ⇨ LATEST AEFI BULLETINS PUBLISHED IN THE REGION
		PUBLICATIONS ON POTENTIAL SAFETY SIGNALS IDENTIFIED WITH THE USE OF COVID-19 VACCINES	⇨ Evaluation of acute adverse events after COVID-19 vaccination during pregnancy ⇨ Safety of primary and heterologous booster schedules with ChAdOx1-S and BNT162b2 or mRNA-1273 vaccines: nationwide cohort study ⇨ Assessing case fatality on cases of thrombosis with concurrent thrombocytopenia following COVID-19 vaccine AstraZeneca (Vaxzevria) in the UK: a review of spontaneously reported data ⇨ Effectiveness of BNT162b2 vaccine against Omicron in children 5 to 11 years of age
		DECISIONS OF REGIONAL AND INTERNATIONAL REGULATORY AUTHORITIES	⇨ The International Coalition of Medicines Regulatory Authorities (ICMRA) and the WHO Technical Advisory Group on COVID-19 Vaccine Composition (TAG-CO-VAC) agree on key principles for adapting vaccines to SARS-COV-2 variants. ⇨ The European Center for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA) are recommending expanding the age group for second booster doses of COVID-19 mRNA vaccines. ⇨ The U.S. Food and Drug Administration (FDA) Authorizes Novavax COVID-19 Vaccine ⇨ Health Canada Authorized Use of Moderna's Pediatric Spikevax Vaccine ⇨ The EMA's Committee for Medicinal Products for Human Use (CHMP) recommends expanding the age group in which the Spikevax COVID-19 vaccine can be used as a booster, as well as extending the vaccine's shelf life. ⇨ Chile's Institute of Public Health (ISP) authorizes age range extension starting from 6 months for Pfizer, Sinovac, and Moderna COVID-19 vaccines.
		CLARIFICATIONS/CONCLUSIONS ON EVENTS PRESENTED IN PREVIOUS COMMUNICATIONS	⇨ COVID-19 vaccines Safety Update from the EMA's Pharmacovigilance Risk Assessment Committee (PRAC) ⇨ SAGE/WHO updates interim statement on COVID-19 vaccination for children. ⇨ SAGE/WHO Good practice statement on the use of second booster doses for COVID 19 vaccines ⇨ WHO SAGE updated recommendations for use of Moderna and Pfizer-BioNTech vaccines
		OTHER RELATED UPDATES	⇨ WHO SAGE issues interim recommendations for use of the Valneva VLA2001 against COVID-19

			⇨ The U.S. FDA and Europe's EMA authorize Moderna and Pfizer-BioNTech adapted COVID-19 vaccines ⇨ China's National Medical Products Administration authorizes CanSino's inhaled COVID-19 vaccine ⇨ Invitation to a practical exercises in case series causality assessment course from the Uppsala Monitoring Center (UMC)