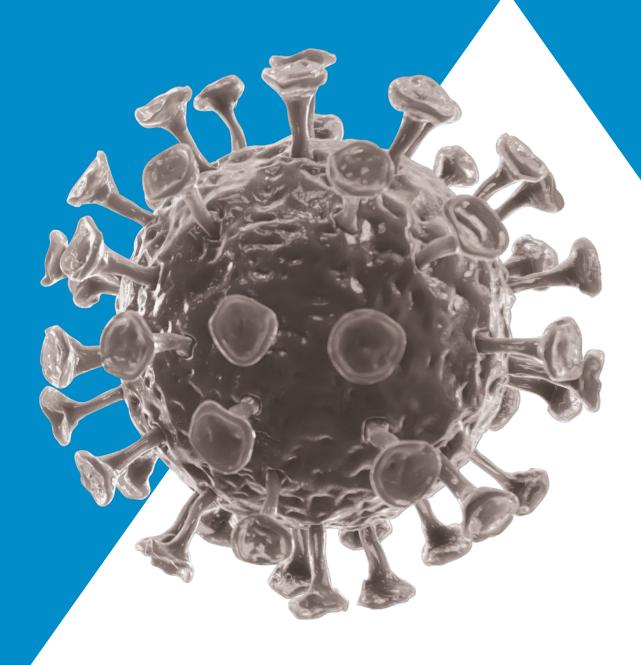
COVID-19 VACCINES:

SAFETY SURVEILLANCE MANUAL



SECOND EDITION



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Abbreviations and acronyms

AACVS African Advisory Committee on Vaccine Safety

ACE Angiotensin-converting enzyme

ACT Access to COVID-19 tools

ADEM Acute disseminated encephalomyelitis

ADRs Adverse drug reactions

AEFI Adverse event following immunization

AESI Adverse event of special interest

ARDS Acute respiratory distress syndrome

AVSS Active vaccine safety surveillance

BMI Body-mass index

CEM Cohort event monitoring

CEPI Coalition for Epidemic Preparedness Innovations

CIOMS Council for International Organizations of Medical Sciences

COVID-19 Coronavirus disease 2019

DCVMN Developing Countries Vaccine Manufactures Network

DL Data linkage

DNA Deoxyribonucleic acid

EH e-Health

EPI Expanded programme on immunization

FIND Foundation for Innovative New Diagnostics

GACVS Global Advisory Committee on Vaccine Safety

GBS Guillain-Barré syndrome

GMP Good manufacturing practices

GVAP Global vaccine action plan

HCW Health care worker

HELLP Haemolysis, elevated liver enzymes, low platelet count

ICD International classification of diseases

ICSR Individual case safety report

IFPMA International Federation of Pharmaceutical Manufacturers and Associations

ISOP International Society of Pharmacovigilance

ISRR Immunization stress-related response

LMIC Low- and middle-income country

LMP Last menstrual period

MedDRA Medical dictionary for regulatory activities

MH m-Health

MoH Ministry of Health
mRNA Messenger RNA

NIP National Immunization Programme

NITAG National Immunization Technical Advisory Group

NRA National regulatory authority

PASS Post-authorization safety studies

PBRER Periodic benefit-risk evaluation report

PER Pregnancy exposure register

PHEIC Public health emergency of international concern
PIDM Programme for International Drug Monitoring

PSUR Periodic safety update report

PV Pharmacovigilance

QPPV Qualified person responsible for pharmacovigilance
RITAG Regional Immunization Technical Advisory Groups

RMP Risk management plan

RNA Ribonucleic acid

SAGE Strategic Advisory Group of Experts (for immunization)

SARS-CoV-2 Severe acute respiratory syndrome coronavirus 2

SKG Significant knowledge gap

SIA Supplementary immunization activities

SS Sentinel surveillance

STI Sexually transmitted infection

TGA Therapeutic Goods Administration (Australian Government Department

of Health)

UMC Uppsala Monitoring Centre (WHO Collaborating Centre for International

Drug Monitoring)

US Ultrasound

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