SIMULATED INDIVIDUAL CASE SAFETY REPORTS (ICSR) – CASE NARRATIVES

PV001 Narrative

A 65-year-old male patient from India was receiving warfarin 5 mg once daily for atrial fibrillation. The patient developed gastrointestinal haemorrhage on 05-Oct-2024 after initiation of therapy. The event was assessed as serious, with hospitalization as the seriousness criterion. Warfarin was discontinued, and a positive dechallenge was reported. The patient recovered. The event was considered expected and had a possible causal relationship with warfarin as per WHO-UMC criteria.

PV002 Narrative

A 58-year-old female patient from the USA was receiving metformin 500 mg twice daily for type 2 diabetes mellitus. The patient developed lactic acidosis on 01-Sep-2024 following treatment initiation. The event was assessed as serious and life-threatening. Metformin was discontinued, and the patient showed clinical improvement. The event was considered unexpected and had a probable causal relationship with metformin.

PV003 Narrative

A 42-year-old male patient from India was receiving amoxicillin 500 mg three times daily for upper respiratory tract infection. The patient developed rash on 03-Oct-2024. The event was non-serious, and amoxicillin was discontinued. The patient recovered. The event was considered expected and had a probable causal relationship with amoxicillin.

PV004 Narrative

A 70-year-old female patient from the United Kingdom was receiving diclofenac 50 mg twice daily for osteoarthritis. The patient developed acute kidney injury on 25-Sep-2024. The event was assessed as serious and medically significant. Diclofenac was discontinued, and the patient was recovering at the

time of reporting. The event was considered expected and had a possible causal relationship with diclofenac.

PV005 Narrative

A 34-year-old female patient from India was receiving levofloxacin 500 mg once daily for urinary tract infection. The patient developed tendinitis on 07-Oct-2024. The event was assessed as serious with disability as the seriousness criterion. Levofloxacin was discontinued, and the patient was recovering. The event was considered unexpected and had a probable causal relationship with levofloxacin.

PV006 Narrative

A 60-year-old male patient from Canada was receiving atorvastatin 40 mg once daily for dyslipidaemia. The patient developed rhabdomyolysis on 20-Jul-2024 after initiation of therapy. The event was assessed as serious, with hospitalization as the seriousness criterion. Atorvastatin was discontinued, and a positive dechallenge was reported. The patient was recovering at the time of reporting. The event was considered unexpected and had a probable causal relationship with atorvastatin.

PV007 Narrative

A 55-year-old female patient from India was receiving carbamazepine 200 mg twice daily for epilepsy. The patient developed Stevens–Johnson syndrome on 01-Jul-2024 after treatment initiation. The event was assessed as serious and life-threatening. Carbamazepine was discontinued immediately, and the patient was managed in hospital. The patient was recovering at the time of reporting. The event was considered expected and had a probable causal relationship with carbamazepine.

PV008 Narrative

A 68-year-old male patient from Germany was receiving clopidogrel 75 mg once daily for post-myocardial infarction management. The patient developed epistaxis on 25-May-2024. The event was assessed as serious and medically significant. Clopidogrel was continued with monitoring. The patient recovered.

The event was considered expected and had a possible causal relationship with clopidogrel.

PV009 Narrative

A 29-year-old female patient from India was receiving isotretinoin 20 mg once daily for acne vulgaris. The patient developed symptoms of depression on 01-Jun-2024 following prolonged therapy. The event was assessed as serious and medically significant. Isotretinoin was discontinued, and the patient showed improvement. The event was considered expected and had a possible causal relationship with isotretinoin.

PV010 Narrative

A 75-year-old male patient from the USA was receiving digoxin 0.25 mg once daily for heart failure. The patient developed bradycardia on 20-Mar-2024. The event was assessed as serious, with hospitalization as the seriousness criterion. Digoxin was discontinued, and the patient recovered. The event was considered expected and had a probable causal relationship with digoxin.

PV011 Narrative

A 3-year-old male patient from India was receiving paracetamol 250 mg three times daily for fever. An overdose was reported on 02-Oct-2024. The event was assessed as serious, with hospitalization as the seriousness criterion. Paracetamol was discontinued, and appropriate treatment was provided. The patient recovered. The event was considered expected and had a probable causal relationship with paracetamol.

PV012 Narrative

A 45-year-old female patient from France received an influenza vaccine 0.5 mL intramuscularly for immunization. The patient developed anaphylaxis on the same day of vaccination. The event was assessed as serious and life-threatening. The patient received immediate medical management and recovered. The event

was considered unexpected and had a probable causal relationship with the influenza vaccine.

PV013 Narrative

A 62-year-old male patient from India was receiving cisplatin 75 mg/m² intravenously for lung cancer. The patient developed nephrotoxicity on 20-Aug-2024 during treatment. The event was assessed as serious, with hospitalization as the seriousness criterion. Cisplatin was discontinued, and the patient was recovering at the time of reporting. The event was considered expected and had a probable causal relationship with cisplatin.

PV014 Narrative

A 30-year-old female patient from the USA was consuming a herbal weight loss product for obesity. The patient developed hepatotoxicity on 05-Aug-2024. The event was assessed as serious, with hospitalization as the seriousness criterion. The product was discontinued, and the patient was recovering. The event was considered unexpected and had a possible causal relationship with the herbal product.

PV015 Narrative

A 28-year-old female patient from India was receiving valproate 500 mg twice daily for epilepsy during pregnancy. A congenital anomaly was reported in the new born on 01-Dec-2024. The event was assessed as serious, with congenital anomaly as the seriousness criterion. Valproate exposure was continued during pregnancy. The outcome was ongoing. The event was considered expected and had a probable causal relationship with valproate.

PV016 Narrative

A 50-year-old male patient from Japan was receiving amlodipine 5 mg once daily for hypertension. Lack of efficacy was reported on 01-Jun-2024 due to inadequate blood pressure control. The event was assessed as non-serious. Amlodipine was continued with addition of another antihypertensive agent. The

event was considered expected and had a possible causal relationship with amlodipine.

PV017 Narrative

A 67-year-old male patient from India was receiving insulin for type 2 diabetes mellitus. The patient developed hypoglycaemia on 10-Mar-2024. The event was assessed as serious, with hospitalization as the seriousness criterion. Insulin dose was adjusted, and the patient recovered. The event was considered expected and had a probable causal relationship with insulin.

PV018 Narrative

A 40-year-old female patient from the United Kingdom was receiving ibuprofen 400 mg three times daily for pain. A medication error was reported on 10-Feb-2024 due to incorrect dosing. The event was assessed as non-serious. The error was corrected, and the patient recovered. The event was considered expected and had an unlikely causal relationship with ibuprofen.

PV019 Narrative

A 72-year-old male patient from India was receiving rivaroxaban 20 mg once daily for deep vein thrombosis. The patient developed intracranial hemorrhage on 25-Jan-2024. The event was assessed as serious and fatal, with death as the seriousness criterion. Rivaroxaban was discontinued. The event was considered expected and had a probable causal relationship with rivaroxaban.

PV020 Narrative

A 35-year-old female patient from the USA was receiving azithromycin 500 mg once daily for respiratory tract infection. The patient developed QT prolongation on 05-Nov-2024. The event was assessed as serious and medically significant. Azithromycin was discontinued, and the patient recovered. The event was considered expected and had a probable causal relationship with azithromycin.