

Serious Safety Signals and Prediction Features Following COVID-19 mRNA Vaccines Using the Vaccine Adverse Event Reporting System

Supplementary Appendix

Table of contents

| | |
|---|----|
| Figure S1. Selection of Individual case safety reports..... | 2 |
| Figure S2. Selection of adverse events following immunization. | 3 |
| Table S1. Definition and criteria of disproportionality analysis for signal detection..... | 4 |
| Table S2. List of highly reported patient medical history in VAERS. | 5 |
| Table S3. Clinical consequences of serious ICSRs after mRNA-based COVID-19 vaccination (n=555,033).6 | |
| Table S4. Percentage changes between serious AEFIs and non-serious AEFIs by SOC after mRNA-based COVID-19 vaccination. | 7 |
| Table S5. Signals detected from adverse events after administration of Pfizer-BioNTech (BNT162b2)..... | 8 |
| Table S6. Signals detected in adverse events after administration of Moderna (mRNA-1273)..... | 13 |
| Table S7. Signals detected from serious adverse events after administration of Pfizer-BioNTech (BNT162b2)..... | 16 |
| Table S8. Signals detected from serious adverse events after administration of Moderna (mRNA-1273)..... | 17 |
| Table S9. Area under the receiver operating characteristic curve (AUROC) with various numbers of selected features in major signals of AEFIs..... | 18 |

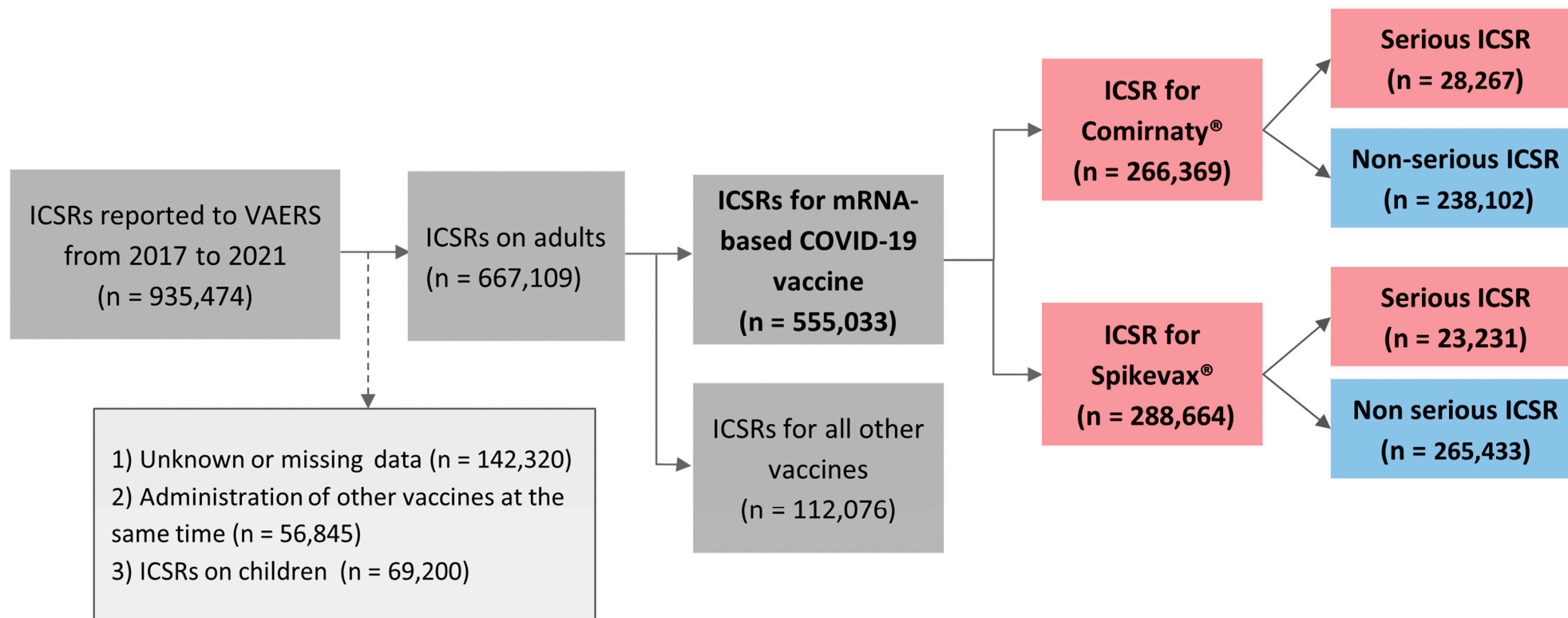


Figure S1. Selection of Individual case safety reports.

COVID-19: corona virus infectious disease-19; ICSR: individual case safety report; VAERS: vaccine adverse event reporting system

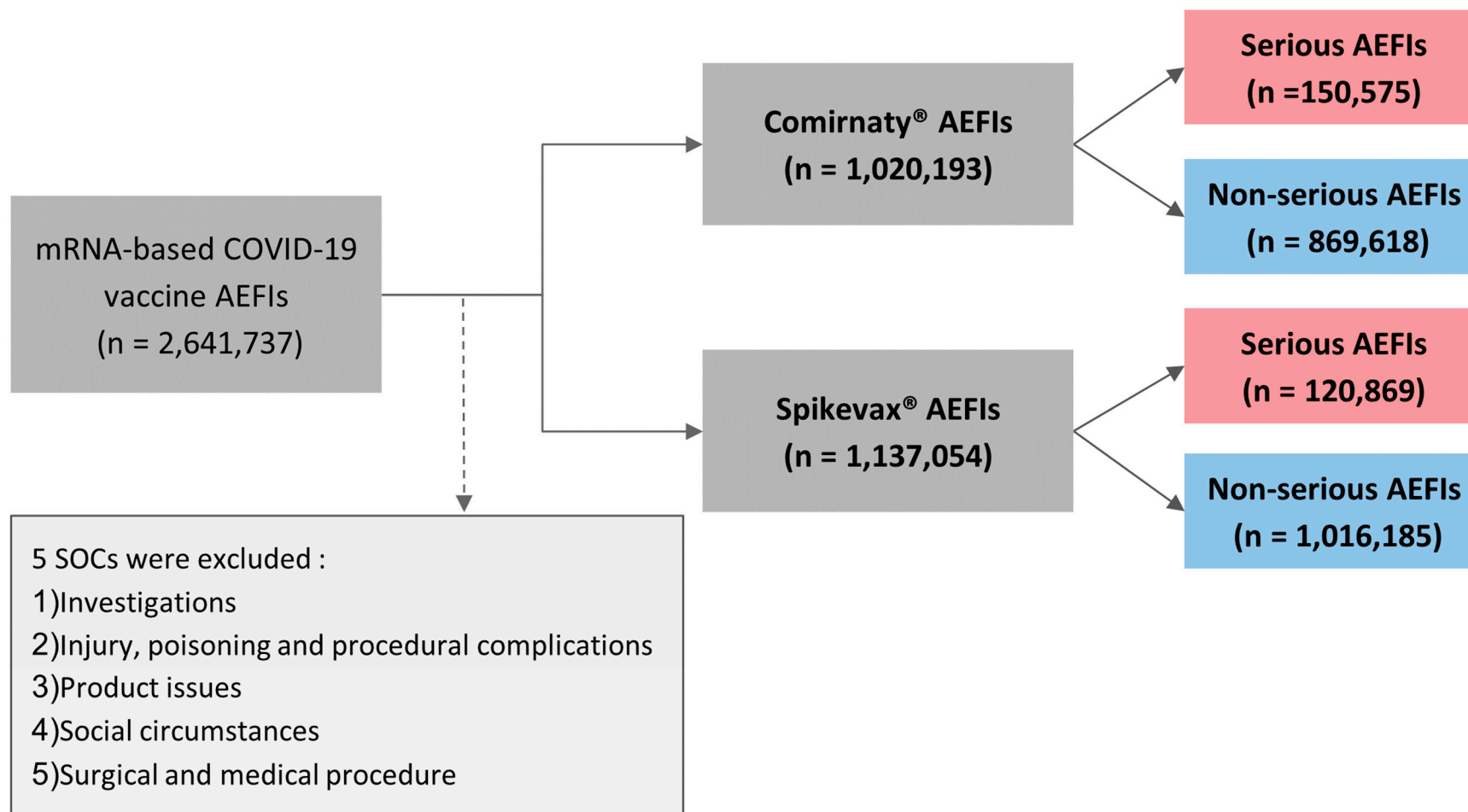


Figure S2. Selection of adverse events following immunization.

AEFI: adverse events after immunization; COVID-19: corona virus infectious disease-19; SOC: system organ class

Table S1. Definition and criteria of disproportionality analysis for signal detection.

| Number of reports | A specific AE | All other AEs |
|---------------------|---------------|---------------|
| Target mRNA vaccine | A | B |
| All other vaccines | C | D |

AE = adverse event

| Measures | Calculation | Criteria as signal |
|----------|---|---------------------------------------|
| PRR | $PRR = (A / (A + B)) / (C / (C + D))$ | $PRR \geq 2, \chi^2 \geq 4, N \geq 3$ |
| ROR | $ROR = (A / B) / (C / D)$ | lower limit of 95% CI >1, $N \geq 3$ |
| BCPNN | $IC = \log_2 \frac{P(AE, Drug)}{P(AE)P(Drug)}$ | Lower limit of 95% CI ≥ 0 |
| | $95\% \text{ CI} = E(IC) \pm 2V(IC)^{0.5}$ | |
| MGPS | $EBGM = A(A+B+C+D)/(A+C)/(A+B)$ | Lower limit of 95% CI >1 |
| | $95\% \text{ CI} = e^{\ln(EBGM) \pm 1.96(1/A + 1/B + 1/C + 1/D)^{0.5}}$ | |

AE: adverse event; PRR: proportional reporting ratio; ROR: reporting odd ratio; MGPS: multi-item Gamma Poisson shrinker; BCPNN: Bayesian confidence propagation neural network, IC: information component; EBGM = empirical Bayesian geometric mean; A: The number of a specific adverse event after each mRNA vaccine; B: The number of other adverse events after each mRNA vaccine; C: The number of a specific adverse event after all other vaccines; D: The number of other adverse events after all other vaccines; χ^2 = chi-square

Table S2. List of highly reported patient medical history in VAERS.

| | Disease |
|----|---|
| 1 | Acute kidney injury |
| 2 | Anaemia |
| 3 | Aneurysm |
| 4 | Anxiety |
| 5 | Arrhythmia |
| 6 | Arthritis |
| 7 | Asthma |
| 8 | Benign prostatic hyperplasia |
| 9 | Cerebrovascular accident |
| 10 | Chronic kidney disease |
| 11 | Chronic obstructive pulmonary disease |
| 12 | Coronary artery disease |
| 13 | Crohn's disease |
| 14 | Deep vein thrombosis or Pulmonary embolism |
| 15 | Dementia |
| 16 | Depression |
| 17 | Fibromyalgia |
| 18 | Gastrooesophageal reflux disease |
| 19 | Heart failure |
| 20 | Hepatobiliary disorders |
| 21 | Hyperlipidemia |
| 22 | Hypertension |
| 23 | Hyperthyroidism |
| 24 | Hypothyroidism |
| 25 | Irritable bowel syndrome |
| 26 | Migraine |
| 27 | Multiple sclerosis |
| 28 | Myocardial infarction |
| 29 | Neoplasms benign, malignant and unspecified (incl cysts and polyps) |
| 30 | Osteoporosis |
| 31 | Polycystic ovaries |
| 32 | Pulmonary hypertension |
| 33 | Seizure |
| 34 | Sleep apnoea syndrome |
| 35 | Type 1 diabetes mellitus |
| 36 | Type 2 diabetes mellitus |

Table S3. Clinical consequences of serious ICSRs after mRNA-based COVID-19 vaccination (n=555,033).

| Category | | Pfizer-BioNTech (BNT162b2) | | Moderna (mRNA-1273) | | P-value |
|-------------------------|------------------------------------|----------------------------|--------|---------------------|--------|---------|
| | | n | % | n | % | |
| ICSRs | | 266,369 | 100.00 | 288,664 | 100.00 | p<.0000 |
| Non-serious ICSRs | | 238,102 | 89.39 | 265,433 | 91.95 | |
| Serious ICSRs | | 28,267 | 10.61 | 23,231 | 8.05 | |
| | Type of serious ICSRs [†] | | | | | p<.0000 |
| Death | | 3,924 | 1.47 | 3,840 | 1.33 | |
| Life-threatening | | 4,899 | 1.84 | 4,118 | 1.43 | |
| Hospitalized/ prolonged | | 21,073 | 7.91 | 17,121 | 5.93 | |
| Disability | | 5,605 | 2.10 | 4,140 | 1.43 | |
| AEFIs | | 1,020,193 | 100.00 | 1,137,054 | 100.00 | p<.0000 |
| Non-serious AEFIs | | 869,618 | 85.24 | 1,016,185 | 89.37 | |
| Serious AEFIs | | 150,575 | 14.76 | 120,869 | 10.63 | |

ICSR= individual case safety report; AEFI=adverse events after immunization

†: A report may meet more than one criterion for classification as type of seriousness

Table S4. Percentage changes between serious AEFIs and non-serious AEFIs by SOC after mRNA-based COVID-19 vaccination.

| SOC | Pfizer-BioNTech (BNT162b2) | | | | Change | Moderna (mRNA-1273) | | | | Change |
|--|------------------------------------|-------------|--------------------------------|--------------|------------|--------------------------------------|-------------|--------------------------------|-------------|------------|
| | Non-serious AEFIs (n = 869,618) | | Serious AEFIs (n = 150,575) | | | Non-serious AEFIs (n = 1,016,185) | | Serious AEFIs (n = 120,869) | | |
| | n | % | n | % | | n | % | n | % | |
| Hepatobiliary disorders | 289 | 0.03 | 642 | 0.43 | 1183 | 267 | 0.03 | 555 | 0.46 | 1648 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 438 | 0.05 | 561 | 0.37 | 640 | 412 | 0.04 | 429 | 0.35 | 775 |
| Renal and urinary disorders | 2,224 | 0.26 | 2,527 | 1.68 | 556 | 2,436 | 0.24 | 1,895 | 1.57 | 554 |
| Congenital, familial and genetic disorders | 143 | 0.02 | 145 | 0.10 | 486 | 127 | 0.01 | 110 | 0.09 | 628 |
| Infections and infestations | 22,146 | 2.55 | 16,898 | 11.22 | 341 | 17,988 | 1.77 | 11,406 | 9.44 | 433 |
| Cardiac disorders | 13,991 | 1.61 | 9,053 | 6.01 | 274 | 11,083 | 1.09 | 7,530 | 6.23 | 471 |
| Pregnancy, puerperium and perinatal conditions | 1,052 | 0.12 | 675 | 0.45 | 271 | 737 | 0.07 | 366 | 0.30 | 318 |
| Metabolism and nutrition disorders | 5,993 | 0.69 | 3,456 | 2.30 | 233 | 7,297 | 0.72 | 2,710 | 2.24 | 212 |
| Endocrine disorders | 563 | 0.06 | 241 | 0.16 | 147 | 399 | 0.04 | 173 | 0.14 | 265 |
| Respiratory, thoracic and mediastinal disorders | 56,750 | 6.53 | 22,109 | 14.68 | 125 | 44,420 | 4.37 | 16,532 | 13.68 | 213 |
| Vascular disorders | 15,342 | 1.76 | 4,185 | 2.78 | 58 | 12,665 | 1.25 | 3,566 | 2.95 | 137 |
| Immune system disorders | 3,413 | 0.39 | 759 | 0.50 | 28 | 2,837 | 0.28 | 527 | 0.44 | 56 |
| Psychiatric disorders | 19,630 | 2.26 | 4,063 | 2.70 | 20 | 18,683 | 1.84 | 3,404 | 2.82 | 53 |
| Ear and labyrinth disorders | 15,604 | 1.79 | 2,399 | 1.59 | -11 | 12,326 | 1.21 | 1,747 | 1.45 | 19 |
| Eye disorders | 15,851 | 1.82 | 2,355 | 1.56 | -14 | 13,260 | 1.30 | 1,975 | 1.63 | 25 |
| Nervous system disorders | 153,620 | 17.67 | 21,790 | 14.47 | -18 | 144,354 | 14.21 | 17,961 | 14.86 | 5 |
| Blood and lymphatic system disorders | 14,300 | 1.64 | 1,983 | 1.32 | -20 | 11,179 | 1.10 | 1,586 | 1.31 | 19 |
| Gastrointestinal disorders | 77,817 | 8.95 | 10,455 | 6.94 | -22 | 77,148 | 7.59 | 8,446 | 6.99 | -8 |
| General disorders and administration site conditions | 273,959 | 31.50 | 32,699 | 21.72 | -31 | 418,866 | 41.22 | 28,450 | 23.54 | -43 |
| Musculoskeletal and connective tissue disorders | 90,784 | 10.44 | 9,463 | 6.28 | -40 | 104,338 | 10.27 | 7,679 | 6.35 | -38 |
| Skin and subcutaneous tissue disorders | 71,119 | 8.18 | 3,419 | 2.27 | -72 | 106,550 | 10.49 | 3,356 | 2.78 | -74 |
| Reproductive system and breast disorders | 14,590 | 1.68 | 698 | 0.46 | -72 | 8,813 | 0.87 | 466 | 0.39 | -56 |

AEFI: adverse events after immunization; SOC :system organ class.

Change (%) was calculated by subtracting proportion of non-serious AEFIs from proportion of serious AEFIs and dividing it by proportion of non-serious AEFIs.

Table S5. Signals detected from adverse events after administration of Pfizer-BioNTech (BNT162b2).

| SOC | PT (n = 201) | Count | PRR | ROR | IC _{LB} | EBGM _{LB} |
|--------------------------------------|--------------------------------|--------|-------|--------------|------------------|--------------------|
| Blood and lymphatic system disorders | Lymphadenopathy | 11,189 | 3.65 | 3.68 | 0.34 | 1.28 |
| | Thrombocytopenia | 354 | 3.04 | 3.04 | 0.13 | 1.16 |
| | Lymph node pain | 2,621 | 3.01 | 3.02 | 0.27 | 1.23 |
| Cardiac disorders | Acute myocardial infarction | 485 | 12.48 | 12.49 | 0.31 | 1.30 |
| | Coronary artery occlusion | 91 | 10.54 | 10.54 | 0.05 | 1.16 |
| | Cardiac flutter | 649 | 8.59 | 8.60 | 0.32 | 1.30 |
| | Cardiomegaly | 295 | 8.54 | 8.54 | 0.24 | 1.25 |
| | Atrial flutter | 122 | 8.07 | 8.08 | 0.10 | 1.18 |
| | Supraventricular extrasystoles | 130 | 7.53 | 7.53 | 0.10 | 1.18 |
| | Cardiomyopathy | 106 | 7.02 | 7.02 | 0.06 | 1.15 |
| | Angina pectoris | 542 | 6.98 | 6.98 | 0.28 | 1.27 |
| | Cardiac disorder | 416 | 6.42 | 6.43 | 0.25 | 1.25 |
| | Myocardial infarction | 660 | 6.00 | 6.00 | 0.29 | 1.27 |
| | Extrasystoles | 265 | 5.85 | 5.85 | 0.19 | 1.22 |
| | Cardiac failure congestive | 331 | 5.68 | 5.68 | 0.21 | 1.23 |
| | Supraventricular tachycardia | 229 | 5.58 | 5.59 | 0.17 | 1.20 |
| | Cardiac failure | 212 | 5.17 | 5.17 | 0.15 | 1.19 |
| | Ventricular extrasystoles | 442 | 5.12 | 5.12 | 0.23 | 1.24 |
| | Sinus tachycardia | 278 | 4.95 | 4.95 | 0.18 | 1.20 |
| | Cardiac discomfort | 147 | 4.86 | 4.87 | 0.08 | 1.15 |
| | Cardiac arrest | 523 | 4.66 | 4.66 | 0.24 | 1.23 |
| | Atrial fibrillation | 1,307 | 4.36 | 4.36 | 0.29 | 1.26 |
| | Pericarditis | 866 | 4.31 | 4.32 | 0.27 | 1.25 |
| | Pericardial effusion | 288 | 4.30 | 4.31 | 0.17 | 1.19 |
| | Myocarditis | 962 | 3.98 | 3.98 | 0.26 | 1.24 |
| | Cardio-respiratory arrest | 145 | 3.95 | 3.95 | 0.05 | 1.13 |
| | Bradycardia | 353 | 3.89 | 3.90 | 0.18 | 1.19 |
| | Palpitations | 7,137 | 3.84 | 3.87 | 0.34 | 1.28 |
| | Arrhythmia | 512 | 3.71 | 3.71 | 0.20 | 1.21 |
| | Tachycardia | 2,908 | 3.57 | 3.58 | 0.30 | 1.26 |
| Ear and labyrinth disorders | Ear discomfort | 1,372 | 4.30 | 4.30 | 0.29 | 1.26 |
| | Tinnitus | 6,935 | 4.23 | 4.25 | 0.35 | 1.29 |
| | Vertigo | 3,796 | 2.63 | 2.64 | 0.25 | 1.21 |
| | Hypoacusis | 693 | 2.57 | 2.57 | 0.16 | 1.16 |
| | Hyperacusis | 334 | 2.34 | 2.35 | 0.07 | 1.11 |
| | Deafness | 706 | 2.32 | 2.32 | 0.14 | 1.14 |
| | Ear pain | 1,852 | 2.05 | 2.05 | 0.17 | 1.15 |
| Eye disorders | Eye haemorrhage | 146 | 4.83 | 4.83 | 0.08 | 1.15 |
| | Blepharospasm | 308 | 3.48 | 3.48 | 0.14 | 1.17 |
| | Vitreous floaters | 289 | 3.27 | 3.27 | 0.12 | 1.16 |
| | Asthenopia | 190 | 3.04 | 3.04 | 0.06 | 1.12 |
| | Ocular discomfort | 405 | 2.76 | 2.76 | 0.13 | 1.15 |
| Gastrointestinal disorders | Gastrointestinal haemorrhage | 181 | 8.39 | 8.39 | 0.17 | 1.21 |
| | Tongue pruritus | 286 | 5.30 | 5.30 | 0.19 | 1.21 |
| | Paraesthesia oral | 3,500 | 3.68 | 3.69 | 0.31 | 1.26 |
| | Hypoaesthesia oral | 2,491 | 3.68 | 3.68 | 0.30 | 1.26 |
| | Tongue discomfort | 292 | 3.38 | 3.38 | 0.13 | 1.16 |

| SOC | PT (n = 201) | Count | PRR | ROR | IC _{LB} | EBGM _{LB} |
|--|---------------------------------------|--------|--------|---------------|------------------|--------------------|
| | Haematochezia | 263 | 2.97 | 2.97 | 0.10 | 1.14 |
| | Oral pruritus | 275 | 2.90 | 2.90 | 0.10 | 1.14 |
| | Tongue disorder | 259 | 2.86 | 2.86 | 0.09 | 1.13 |
| | Swollen tongue | 2,282 | 2.68 | 2.69 | 0.24 | 1.20 |
| | Abdominal pain lower | 375 | 2.56 | 2.56 | 0.11 | 1.13 |
| | Oral discomfort | 387 | 2.36 | 2.36 | 0.09 | 1.12 |
| | Gastrooesophageal reflux disease | 368 | 2.30 | 2.30 | 0.08 | 1.11 |
| | Dyspepsia | 810 | 2.23 | 2.23 | 0.14 | 1.14 |
| | Dry mouth | 995 | 2.14 | 2.15 | 0.14 | 1.14 |
| | Abdominal distension | 781 | 2.10 | 2.10 | 0.12 | 1.13 |
| | Abdominal pain | 3,210 | 2.08 | 2.09 | 0.19 | 1.16 |
| | Mouth swelling | 453 | 2.06 | 2.06 | 0.07 | 1.10 |
| | Dysphagia | 2,453 | 2.05 | 2.05 | 0.18 | 1.15 |
| General disorders and administration site conditions | Disease recurrence | 189 | 87.57 | 87.58 | 0.24 | 1.28 |
| | Vaccination site pruritus | 596 | 16.24 | 16.25 | 0.34 | 1.33 |
| | Drug ineffective | 754 | 15.19 | 15.20 | 0.36 | 1.33 |
| | Facial discomfort | 133 | 6.85 | 6.85 | 0.10 | 1.17 |
| | Illness | 1,426 | 6.67 | 6.68 | 0.35 | 1.31 |
| | Death | 4,033 | 5.82 | 5.84 | 0.38 | 1.32 |
| | General physical health deterioration | 350 | 5.79 | 5.79 | 0.22 | 1.23 |
| | Vaccination site mass | 381 | 5.19 | 5.19 | 0.22 | 1.23 |
| | Vaccination site erythema | 1,073 | 5.07 | 5.08 | 0.30 | 1.27 |
| | Vaccination site pain | 5,135 | 4.76 | 4.78 | 0.36 | 1.30 |
| | Therapeutic response unexpected | 187 | 3.94 | 3.94 | 0.09 | 1.15 |
| | Chest pain | 10,518 | 3.41 | 3.44 | 0.33 | 1.27 |
| | Chest discomfort | 7,688 | 3.38 | 3.40 | 0.32 | 1.26 |
| | Feeling jittery | 319 | 2.74 | 2.74 | 0.10 | 1.14 |
| | Condition aggravated | 6,965 | 2.59 | 2.60 | 0.27 | 1.22 |
| | Sensation of foreign body | 561 | 2.18 | 2.18 | 0.11 | 1.12 |
| | Vaccination site rash | 380 | 2.10 | 2.10 | 0.06 | 1.10 |
| Immune system disorders | Immunodeficiency | 400 | 5.79 | 5.79 | 0.24 | 1.24 |
| | Anaphylactic reaction | 966 | 2.12 | 2.12 | 0.14 | 1.14 |
| Infections and infestations | Asymptomatic COVID-19 | 588 | 136.21 | 136.29 | 0.38 | 1.36 |
| | COVID-19 pneumonia | 1,903 | 58.78 | 58.89 | 0.45 | 1.40 |
| | Vaccine breakthrough infection | 1,584 | 45.87 | 45.94 | 0.43 | 1.39 |
| | COVID-19 | 18,765 | 44.82 | 45.64 | 0.51 | 1.43 |
| | Appendicitis | 406 | 20.90 | 20.91 | 0.32 | 1.31 |
| | Suspected COVID-19 | 209 | 10.76 | 10.76 | 0.21 | 1.24 |
| | Ear infection | 195 | 3.93 | 3.93 | 0.10 | 1.15 |
| | Sinusitis | 466 | 2.57 | 2.57 | 0.13 | 1.15 |
| | Urinary tract infection | 706 | 2.35 | 2.35 | 0.14 | 1.15 |
| | Sepsis | 536 | 2.24 | 2.24 | 0.11 | 1.13 |
| | Pneumonia | 1,446 | 2.21 | 2.21 | 0.17 | 1.16 |
| Metabolism and nutrition disorders | Hyperglycaemia | 148 | 5.71 | 5.71 | 0.10 | 1.17 |
| | Hypokalaemia | 144 | 4.77 | 4.77 | 0.08 | 1.15 |
| | Hyponatraemia | 333 | 4.68 | 4.68 | 0.19 | 1.21 |
| | Hypophagia | 353 | 2.77 | 2.77 | 0.12 | 1.14 |

| SOC | PT (n = 201) | Count | PRR | ROR | IC _{LB} | EBGM _{LB} |
|---|----------------------------|-------|-------|--------------|------------------|--------------------|
| Musculoskeletal and connective tissue disorders | Costochondritis | 119 | 13.78 | 13.79 | 0.12 | 1.20 |
| | Axillary mass | 461 | 2.43 | 2.43 | 0.12 | 1.13 |
| | Muscle twitching | 1,164 | 2.07 | 2.08 | 0.15 | 1.14 |
| Nervous system disorders | Anosmia | 2,052 | 24.38 | 24.42 | 0.43 | 1.38 |
| | Cerebral infarction | 171 | 13.20 | 13.21 | 0.19 | 1.23 |
| | Ageusia | 2,415 | 12.71 | 12.74 | 0.42 | 1.36 |
| | Taste disorder | 943 | 7.80 | 7.81 | 0.34 | 1.31 |
| | Parosmia | 688 | 7.24 | 7.25 | 0.31 | 1.29 |
| | Electric shock sensation | 390 | 7.23 | 7.23 | 0.26 | 1.26 |
| | Bell's palsy | 1,659 | 6.99 | 7.00 | 0.36 | 1.32 |
| | Ischaemic stroke | 192 | 5.93 | 5.93 | 0.15 | 1.19 |
| | Cerebrovascular accident | 1,306 | 4.76 | 4.77 | 0.31 | 1.27 |
| | Cerebral haemorrhage | 189 | 4.38 | 4.38 | 0.11 | 1.16 |
| | Dysgeusia | 2,273 | 3.71 | 3.71 | 0.30 | 1.26 |
| | Movement disorder | 720 | 3.40 | 3.41 | 0.22 | 1.21 |
| | Transient ischaemic attack | 306 | 3.02 | 3.02 | 0.12 | 1.15 |
| | Head discomfort | 1,457 | 2.97 | 2.98 | 0.24 | 1.21 |
| | Dizziness postural | 322 | 2.71 | 2.71 | 0.10 | 1.13 |
| | Migraine | 3,990 | 2.70 | 2.71 | 0.26 | 1.22 |
| | Hemiparesis | 403 | 2.63 | 2.63 | 0.12 | 1.14 |
| | Aphasia | 763 | 2.56 | 2.56 | 0.17 | 1.17 |
| | Cognitive disorder | 390 | 2.54 | 2.55 | 0.11 | 1.13 |
| | Unresponsive to stimuli | 1,811 | 2.45 | 2.45 | 0.21 | 1.18 |
| | Neurological symptom | 311 | 2.36 | 2.36 | 0.07 | 1.11 |
| | Memory impairment | 792 | 2.24 | 2.24 | 0.14 | 1.14 |
| | Dysarthria | 720 | 2.06 | 2.06 | 0.11 | 1.12 |
| Pregnancy, puerperium and perinatal conditions | Abortion spontaneous | 689 | 4.20 | 4.20 | 0.25 | 1.23 |
| Psychiatric disorders | Panic attack | 635 | 3.98 | 3.98 | 0.23 | 1.22 |
| | Anxiety | 3,870 | 3.32 | 3.33 | 0.30 | 1.25 |
| | Mental status changes | 623 | 3.10 | 3.10 | 0.19 | 1.19 |
| | Nervousness | 1,004 | 2.45 | 2.45 | 0.18 | 1.17 |
| | Fear | 317 | 2.26 | 2.26 | 0.06 | 1.10 |
| | Depression | 543 | 2.11 | 2.11 | 0.10 | 1.12 |
| | | | | | | |
| Renal and urinary disorders | Chronic kidney disease | 137 | 10.58 | 10.58 | 0.14 | 1.20 |
| | Acute kidney injury | 1,052 | 10.15 | 10.16 | 0.36 | 1.33 |
| | Haematuria | 181 | 3.65 | 3.65 | 0.08 | 1.14 |
| | Renal failure | 184 | 3.55 | 3.55 | 0.08 | 1.14 |
| | Dysuria | 293 | 2.30 | 2.30 | 0.06 | 1.10 |
| Reproductive system and breast disorders | Oligomenorrhoea | 328 | 50.66 | 50.67 | 0.31 | 1.32 |
| | Premenstrual syndrome | 88 | 40.77 | 40.78 | 0.09 | 1.19 |
| | Postmenopausal haemorrhage | 288 | 33.36 | 33.37 | 0.29 | 1.30 |
| | Menstruation delayed | 654 | 30.30 | 30.32 | 0.37 | 1.35 |
| | Dysmenorrhoea | 1,110 | 28.57 | 28.60 | 0.40 | 1.37 |
| | Polymenorrhoea | 408 | 27.00 | 27.02 | 0.32 | 1.32 |
| | Hypomenorrhoea | 106 | 24.56 | 24.56 | 0.12 | 1.20 |
| | Intermenstrual bleeding | 829 | 24.01 | 24.02 | 0.38 | 1.35 |
| | Heavy menstrual bleeding | 2,604 | 21.17 | 21.22 | 0.44 | 1.39 |
| | Menstruation irregular | 1,935 | 20.38 | 20.41 | 0.43 | 1.38 |
| | Menstrual disorder | 1,464 | 17.85 | 17.87 | 0.41 | 1.36 |
| | | | | | | |

| SOC | PT (n = 201) | Count | PRR | ROR | IC _{LB} | EBGM _{LB} |
|--|--|--------|-------|--------------|------------------|--------------------|
| | Breast mass | 218 | 10.10 | 10.10 | 0.21 | 1.24 |
| | Vaginal haemorrhage | 936 | 10.09 | 10.09 | 0.35 | 1.32 |
| | Breast tenderness | 268 | 6.21 | 6.21 | 0.20 | 1.22 |
| | Amenorrhoea | 374 | 4.81 | 4.81 | 0.21 | 1.22 |
| | Breast swelling | 388 | 3.52 | 3.53 | 0.17 | 1.18 |
| | Pelvic pain | 198 | 3.06 | 3.06 | 0.06 | 1.12 |
| | Breast pain | 994 | 2.69 | 2.69 | 0.20 | 1.18 |
| Respiratory, thoracic and mediastinal disorders | Acute respiratory failure | 1,120 | 34.59 | 34.63 | 0.41 | 1.37 |
| | Lung opacity | 786 | 33.11 | 33.13 | 0.38 | 1.36 |
| | Lung consolidation | 125 | 14.48 | 14.48 | 0.13 | 1.21 |
| | Hypoxia | 1,358 | 13.68 | 13.69 | 0.39 | 1.35 |
| | Pulmonary embolism | 1,421 | 11.97 | 11.99 | 0.39 | 1.35 |
| | Atelectasis | 277 | 11.67 | 11.67 | 0.25 | 1.27 |
| | Throat clearing | 201 | 9.31 | 9.31 | 0.19 | 1.23 |
| | Lung infiltration | 423 | 8.52 | 8.52 | 0.28 | 1.28 |
| | Pulmonary mass | 159 | 7.37 | 7.37 | 0.14 | 1.19 |
| | Pulmonary thrombosis | 269 | 6.92 | 6.93 | 0.21 | 1.23 |
| | Pleural effusion | 420 | 6.28 | 6.28 | 0.25 | 1.25 |
| | Chronic obstructive pulmonary disease | 261 | 5.76 | 5.76 | 0.19 | 1.22 |
| | Oropharyngeal discomfort | 692 | 5.62 | 5.63 | 0.28 | 1.27 |
| | Pharyngeal paraesthesia | 522 | 5.15 | 5.15 | 0.25 | 1.24 |
| | Dyspnoea exertional | 774 | 4.91 | 4.92 | 0.28 | 1.26 |
| | Pulmonary oedema | 245 | 4.73 | 4.73 | 0.16 | 1.19 |
| | Lung disorder | 236 | 4.21 | 4.21 | 0.14 | 1.18 |
| | Epistaxis | 1,013 | 3.91 | 3.91 | 0.26 | 1.24 |
| | Pharyngeal hypoaesthesia | 259 | 3.87 | 3.87 | 0.14 | 1.17 |
| | Hyperventilation | 359 | 3.78 | 3.78 | 0.17 | 1.19 |
| | Paranasal sinus discomfort | 439 | 3.77 | 3.77 | 0.19 | 1.20 |
| | Haemoptysis | 192 | 3.71 | 3.71 | 0.09 | 1.15 |
| | Tachypnoea | 283 | 3.64 | 3.64 | 0.14 | 1.17 |
| | Respiratory distress | 308 | 3.40 | 3.40 | 0.14 | 1.17 |
| | Pulmonary pain | 247 | 3.18 | 3.18 | 0.10 | 1.14 |
| | Pulmonary congestion | 233 | 3.18 | 3.18 | 0.09 | 1.14 |
| | Nasal congestion | 2,714 | 3.14 | 3.15 | 0.28 | 1.23 |
| | Pharyngeal swelling | 2,145 | 3.14 | 3.14 | 0.27 | 1.23 |
| | Respiratory failure | 365 | 3.13 | 3.13 | 0.14 | 1.16 |
| | Cough | 11,386 | 3.00 | 3.02 | 0.31 | 1.25 |
| | Sinus congestion | 614 | 2.99 | 3.00 | 0.18 | 1.18 |
| | Respiratory tract congestion | 2,132 | 2.91 | 2.92 | 0.25 | 1.22 |
| | Upper-airway cough syndrome | 317 | 2.88 | 2.88 | 0.11 | 1.14 |
| | Rhinorrhoea | 3,438 | 2.81 | 2.82 | 0.26 | 1.22 |
| | Dyspnoea | 19,740 | 2.72 | 2.75 | 0.29 | 1.24 |
| | Dry throat | 439 | 2.71 | 2.71 | 0.13 | 1.15 |
| | Throat tightness | 3,399 | 2.56 | 2.56 | 0.24 | 1.20 |
| | Throat irritation | 3,123 | 2.50 | 2.51 | 0.24 | 1.20 |
| | Sneezing | 911 | 2.37 | 2.37 | 0.16 | 1.16 |
| | Productive cough | 917 | 2.22 | 2.23 | 0.15 | 1.15 |
| | Asthma | 689 | 2.11 | 2.11 | 0.12 | 1.12 |
| | Oropharyngeal pain | 5,642 | 2.08 | 2.09 | 0.21 | 1.17 |

| SOC | PT (n = 201) | Count | PRR | ROR | IC _{LB} | EBGM _{LB} |
|--|-----------------------------|-------|-------|--------------|------------------|--------------------|
| Skin and subcutaneous tissue disorders | Alopecia | 564 | 2.18 | 2.18 | 0.11 | 1.12 |
| | Superficial vein thrombosis | 124 | 57.45 | 57.46 | 0.16 | 1.23 |
| Vascular disorders | Deep vein thrombosis | 1,012 | 13.02 | 13.04 | 0.37 | 1.34 |
| | Thrombosis | 1,582 | 8.24 | 8.25 | 0.37 | 1.33 |
| | Hypertension | 3,051 | 3.83 | 3.84 | 0.31 | 1.27 |
| | Blood pressure fluctuation | 177 | 3.73 | 3.73 | 0.08 | 1.14 |
| | Hot flush | 1,731 | 2.83 | 2.84 | 0.24 | 1.21 |
| | Flushing | 4,370 | 2.61 | 2.62 | 0.25 | 1.21 |
| | Hypotension | 1,746 | 2.01 | 2.01 | 0.16 | 1.14 |

SOC= system organ class; PT= preferred term; PRR = proportional reporting ratio; ROR = reporting odd ratio; IC_{LB} = lower bound of information component 95% confidence interval; EBGM_{LB} = lower bound of empirical bayesian geometric mean 95% confidence interval

Table S6. Signals detected in adverse events after administration of Moderna (mRNA-1273).

| SOC | PT (n = 110) | Count | PRR | ROR | IC _{LB} | EBGM _{LB} |
|--|---------------------------------------|-------|-------|--------------|------------------|--------------------|
| Blood and lymphatic system disorders | Lymphadenopathy | 8,683 | 2.54 | 2.56 | 0.24 | 1.20 |
| | Lymph node pain | 2,035 | 2.10 | 2.10 | 0.16 | 1.14 |
| Cardiac disorders | Acute myocardial infarction | 366 | 8.45 | 8.45 | 0.22 | 1.23 |
| | Cardiomegaly | 236 | 6.13 | 6.13 | 0.14 | 1.18 |
| | Cardiac flutter | 478 | 5.68 | 5.68 | 0.22 | 1.22 |
| | Myocardial infarction | 582 | 4.74 | 4.75 | 0.21 | 1.21 |
| | Cardiac failure congestive | 296 | 4.56 | 4.56 | 0.14 | 1.17 |
| | Supraventricular tachycardia | 194 | 4.24 | 4.25 | 0.08 | 1.14 |
| | Cardiac failure | 181 | 3.96 | 3.96 | 0.06 | 1.12 |
| | Extrasystoles | 194 | 3.84 | 3.84 | 0.06 | 1.13 |
| | Cardiac disorder | 275 | 3.81 | 3.81 | 0.11 | 1.15 |
| | Ventricular extrasystoles | 366 | 3.80 | 3.80 | 0.14 | 1.17 |
| | Atrial fibrillation | 1,232 | 3.68 | 3.69 | 0.23 | 1.21 |
| | Sinus tachycardia | 223 | 3.57 | 3.57 | 0.07 | 1.13 |
| | Angina pectoris | 305 | 3.52 | 3.52 | 0.11 | 1.15 |
| | Cardiac arrest | 433 | 3.46 | 3.46 | 0.15 | 1.16 |
| | Pericardial effusion | 241 | 3.23 | 3.23 | 0.07 | 1.12 |
| | Myocarditis | 761 | 2.82 | 2.83 | 0.16 | 1.16 |
| | Palpitations | 5,692 | 2.75 | 2.76 | 0.25 | 1.20 |
| | Pericarditis | 612 | 2.74 | 2.74 | 0.14 | 1.15 |
| | Tachycardia | 2,451 | 2.70 | 2.71 | 0.22 | 1.19 |
| Ear and labyrinth disorders | Tinnitus | 5,295 | 2.90 | 2.91 | 0.25 | 1.21 |
| | Ear discomfort | 994 | 2.79 | 2.79 | 0.18 | 1.17 |
| | Vertigo | 3,226 | 2.01 | 2.01 | 0.16 | 1.14 |
| Eye disorders | Ocular discomfort | 369 | 2.26 | 2.26 | 0.05 | 1.09 |
| Gastrointestinal disorders | Paraesthesia oral | 2,623 | 2.47 | 2.48 | 0.20 | 1.17 |
| | Hypoaesthesia oral | 1,864 | 2.47 | 2.47 | 0.19 | 1.17 |
| General disorders and administration site conditions | Vaccination site pruritus | 2,929 | 71.62 | 71.80 | 0.42 | 1.36 |
| | Vaccination site urticaria | 226 | 46.97 | 46.98 | 0.21 | 1.25 |
| | Vaccination site erythema | 4,343 | 18.42 | 18.49 | 0.41 | 1.35 |
| | Vaccination site rash | 1,913 | 9.47 | 9.48 | 0.35 | 1.30 |
| | Vaccination site mass | 673 | 8.23 | 8.23 | 0.28 | 1.26 |
| | Illness | 1,903 | 7.99 | 8.00 | 0.34 | 1.29 |
| | Vaccination site movement impairment | 229 | 7.93 | 7.93 | 0.16 | 1.20 |
| | Facial discomfort | 132 | 6.10 | 6.10 | 0.05 | 1.13 |
| | Vaccination site pain | 7,138 | 5.93 | 5.97 | 0.36 | 1.30 |
| | Vaccination site induration | 969 | 5.52 | 5.52 | 0.27 | 1.25 |
| | Vaccination site discolouration | 232 | 5.36 | 5.36 | 0.13 | 1.17 |
| | Death | 3,685 | 4.77 | 4.78 | 0.32 | 1.27 |
| | General physical health deterioration | 283 | 4.20 | 4.20 | 0.13 | 1.16 |
| | Vaccination site reaction | 916 | 4.05 | 4.05 | 0.23 | 1.21 |
| | Therapeutic response unexpected | 204 | 3.85 | 3.86 | 0.07 | 1.13 |
| | Vaccination site warmth | 2,454 | 3.57 | 3.57 | 0.26 | 1.23 |
| | Vaccination site swelling | 3,387 | 3.27 | 3.27 | 0.26 | 1.22 |
| | Chest pain | 7,751 | 2.26 | 2.27 | 0.21 | 1.17 |

| SOC | PT (n = 110) | Count | PRR | ROR | IC _{LB} | EBGM _{LB} |
|---|--------------------------------|--------|-------|--------------|------------------|--------------------|
| Infections and infestations | Chest discomfort | 5,624 | 2.22 | 2.22 | 0.20 | 1.17 |
| | Asymptomatic COVID-19 | 320 | 66.51 | 66.53 | 0.26 | 1.28 |
| | COVID-19 pneumonia | 1,123 | 31.12 | 31.15 | 0.36 | 1.33 |
| | COVID-19 | 11,848 | 25.39 | 25.64 | 0.44 | 1.37 |
| | Vaccine breakthrough infection | 925 | 24.03 | 24.05 | 0.34 | 1.32 |
| | Post-acute COVID-19 syndrome | 215 | 12.77 | 12.77 | 0.18 | 1.22 |
| | Appendicitis | 206 | 9.51 | 9.52 | 0.16 | 1.20 |
| | Urinary tract infection | 775 | 2.32 | 2.32 | 0.12 | 1.13 |
| | Sinusitis | 448 | 2.22 | 2.22 | 0.07 | 1.10 |
| Nervous system disorders | Anosmia | 1,400 | 14.92 | 14.94 | 0.35 | 1.32 |
| | Ageusia | 1,877 | 8.87 | 8.88 | 0.34 | 1.30 |
| | Taste disorder | 938 | 6.96 | 6.97 | 0.29 | 1.26 |
| | Bell's palsy | 1,380 | 5.22 | 5.22 | 0.28 | 1.25 |
| | Electric shock sensation | 301 | 5.01 | 5.01 | 0.15 | 1.18 |
| | Parosmia | 521 | 4.92 | 4.92 | 0.21 | 1.21 |
| | Cerebrovascular accident | 1,267 | 4.15 | 4.15 | 0.25 | 1.23 |
| | Movement disorder | 687 | 2.91 | 2.92 | 0.16 | 1.16 |
| | Dysgeusia | 1,649 | 2.41 | 2.42 | 0.18 | 1.16 |
| | Hypokinesia | 414 | 2.33 | 2.33 | 0.07 | 1.10 |
| | Migraine | 3,612 | 2.19 | 2.20 | 0.19 | 1.16 |
| | Aphasia | 727 | 2.19 | 2.19 | 0.11 | 1.12 |
| | Head discomfort | 1,148 | 2.10 | 2.10 | 0.13 | 1.12 |
| Pregnancy, puerperium and perinatal conditions | Abortion spontaneous | 420 | 2.30 | 2.30 | 0.07 | 1.10 |
| Psychiatric disorders | Panic attack | 459 | 2.58 | 2.58 | 0.10 | 1.13 |
| | Mental status changes | 528 | 2.36 | 2.36 | 0.10 | 1.12 |
| | Anxiety | 2,882 | 2.22 | 2.22 | 0.18 | 1.16 |
| Renal and urinary disorders | Acute kidney injury | 643 | 5.57 | 5.57 | 0.24 | 1.23 |
| Reproductive system and breast disorders | Oligomenorrhoea | 199 | 27.57 | 27.58 | 0.19 | 1.23 |
| | Postmenopausal haemorrhage | 184 | 19.12 | 19.13 | 0.17 | 1.22 |
| | Menstruation delayed | 385 | 16.00 | 16.01 | 0.26 | 1.26 |
| | Dysmenorrhoea | 624 | 14.41 | 14.42 | 0.30 | 1.28 |
| | Polymenorrhoea | 218 | 12.95 | 12.95 | 0.18 | 1.22 |
| | Intermenstrual bleeding | 465 | 12.08 | 12.09 | 0.26 | 1.26 |
| | Heavy menstrual bleeding | 1,487 | 10.84 | 10.86 | 0.34 | 1.30 |
| | Menstruation irregular | 1,097 | 10.36 | 10.37 | 0.32 | 1.29 |
| | Menstrual disorder | 827 | 9.05 | 9.05 | 0.30 | 1.28 |
| | Breast mass | 145 | 6.03 | 6.03 | 0.07 | 1.14 |
| | Vaginal haemorrhage | 514 | 4.97 | 4.97 | 0.21 | 1.21 |
| | Breast tenderness | 211 | 4.39 | 4.39 | 0.09 | 1.15 |
| Respiratory, thoracic and mediastinal disorders | Acute respiratory failure | 727 | 20.15 | 20.16 | 0.32 | 1.30 |
| | Lung opacity | 489 | 18.48 | 18.49 | 0.29 | 1.28 |
| | Pulmonary embolism | 1,308 | 9.89 | 9.90 | 0.33 | 1.30 |
| | Hypoxia | 1,049 | 9.48 | 9.49 | 0.32 | 1.29 |
| | Atelectasis | 198 | 7.48 | 7.48 | 0.13 | 1.18 |
| | Throat clearing | 157 | 6.53 | 6.53 | 0.09 | 1.15 |
| | Lung infiltration | 332 | 6.00 | 6.00 | 0.18 | 1.20 |
| | Pulmonary thrombosis | 250 | 5.77 | 5.77 | 0.15 | 1.18 |
| | Oropharyngeal discomfort | 607 | 4.43 | 4.43 | 0.21 | 1.21 |

| SOC | PT (n = 110) | Count | PRR | ROR | IC _{LB} | EBGM _{LB} |
|--|---------------------------------------|--------|-------|--------------|------------------|--------------------|
| | Chronic obstructive pulmonary disease | 219 | 4.34 | 4.34 | 0.10 | 1.15 |
| | Pleural effusion | 322 | 4.32 | 4.32 | 0.15 | 1.17 |
| | Pulmonary oedema | 228 | 3.95 | 3.95 | 0.09 | 1.14 |
| | Pharyngeal paraesthesia | 355 | 3.14 | 3.14 | 0.11 | 1.14 |
| | Dyspnoea exertional | 537 | 3.06 | 3.06 | 0.15 | 1.16 |
| | Tachypnoea | 253 | 2.92 | 2.92 | 0.06 | 1.11 |
| | Epistaxis | 829 | 2.87 | 2.87 | 0.17 | 1.17 |
| | Paranasal sinus discomfort | 329 | 2.53 | 2.53 | 0.06 | 1.11 |
| | Pharyngeal swelling | 1,748 | 2.29 | 2.29 | 0.17 | 1.15 |
| | Dyspnoea | 16,455 | 2.03 | 2.05 | 0.20 | 1.16 |
| | Nasal congestion | 1,957 | 2.03 | 2.04 | 0.15 | 1.13 |
| Skin and subcutaneous tissue disorders | Mechanical urticaria | 268 | 15.92 | 15.92 | 0.21 | 1.24 |
| | Skin swelling | 414 | 2.65 | 2.65 | 0.10 | 1.12 |
| Vascular disorders | Deep vein thrombosis | 934 | 10.79 | 10.79 | 0.32 | 1.29 |
| | Thrombosis | 1,198 | 5.60 | 5.60 | 0.28 | 1.25 |
| | Hypertension | 2,606 | 2.94 | 2.94 | 0.23 | 1.20 |
| | Hot flush | 1,512 | 2.22 | 2.22 | 0.15 | 1.14 |

SOC= system organ class; PT= preferred term; PRR = proportional reporting ratio; ROR = reporting odd ratio; IC_{LB} = lower bound of information component 95% confidence interval; EBGM_{LB} = lower bound of empirical bayesian geometric mean 95% confidence interval

Table S7. Signals detected from serious adverse events after administration of Pfizer-BioNTech (BNT162b2).

| SOC | PT (n = 28) | Count | PRR | ROR | IC _{LB} | EBGM _{LB} |
|--|---------------------------------------|-------|--------|---------------|------------------|--------------------|
| Cardiac disorders | Acute myocardial infarction | 467 | 10.72 | 10.75 | 0.15 | 1.17 |
| | Myocardial infarction | 526 | 3.83 | 3.84 | 0.09 | 1.12 |
| | Atrial fibrillation | 814 | 3.52 | 3.54 | 0.12 | 1.13 |
| | Cardiac arrest | 510 | 3.17 | 3.18 | 0.07 | 1.10 |
| General disorders and administration site conditions | Death | 4,021 | 3.79 | 3.86 | 0.21 | 1.17 |
| | Unevaluable event | 943 | 3.52 | 3.53 | 0.13 | 1.13 |
| | Condition aggravated | 2,200 | 2.52 | 2.54 | 0.13 | 1.12 |
| | Chest pain | 2,439 | 2.09 | 2.11 | 0.11 | 1.10 |
| Infections and infestations | Vaccine breakthrough infection | 1,155 | 114.93 | 115.81 | 0.25 | 1.23 |
| | COVID-19 | 8,628 | 37.33 | 39.54 | 0.32 | 1.27 |
| | COVID-19 pneumonia | 1,831 | 39.04 | 39.51 | 0.27 | 1.24 |
| | Asymptomatic COVID-19 | 256 | 38.21 | 38.28 | 0.11 | 1.16 |
| | Appendicitis | 354 | 17.61 | 17.65 | 0.14 | 1.16 |
| Nervous system disorders | Cerebrovascular accident | 1,139 | 3.47 | 3.49 | 0.14 | 1.14 |
| Renal and urinary disorders | Acute kidney injury | 1,001 | 7.47 | 7.51 | 0.19 | 1.18 |
| Respiratory, thoracic and mediastinal disorders | Lung opacity | 748 | 22.33 | 22.44 | 0.21 | 1.20 |
| | Acute respiratory failure | 1,100 | 21.89 | 22.05 | 0.24 | 1.22 |
| | Chronic obstructive pulmonary disease | 217 | 10.80 | 10.81 | 0.06 | 1.12 |
| | Atelectasis | 233 | 9.94 | 9.95 | 0.07 | 1.12 |
| | Hypoxia | 1,280 | 9.10 | 9.17 | 0.22 | 1.20 |
| | Pulmonary embolism | 1,237 | 8.21 | 8.27 | 0.21 | 1.19 |
| | Lung infiltration | 408 | 6.09 | 6.10 | 0.11 | 1.14 |
| | Pleural effusion | 359 | 4.87 | 4.88 | 0.08 | 1.12 |
| | Cough | 3,093 | 4.33 | 4.40 | 0.21 | 1.18 |
| | Dyspnoea exertional | 468 | 4.23 | 4.24 | 0.09 | 1.12 |
| | Dyspnoea | 6,042 | 2.47 | 2.53 | 0.16 | 1.13 |
| | Deep vein thrombosis | 603 | 6.92 | 6.95 | 0.15 | 1.16 |
| Vascular disorders | Thrombosis | 645 | 3.93 | 3.94 | 0.11 | 1.13 |

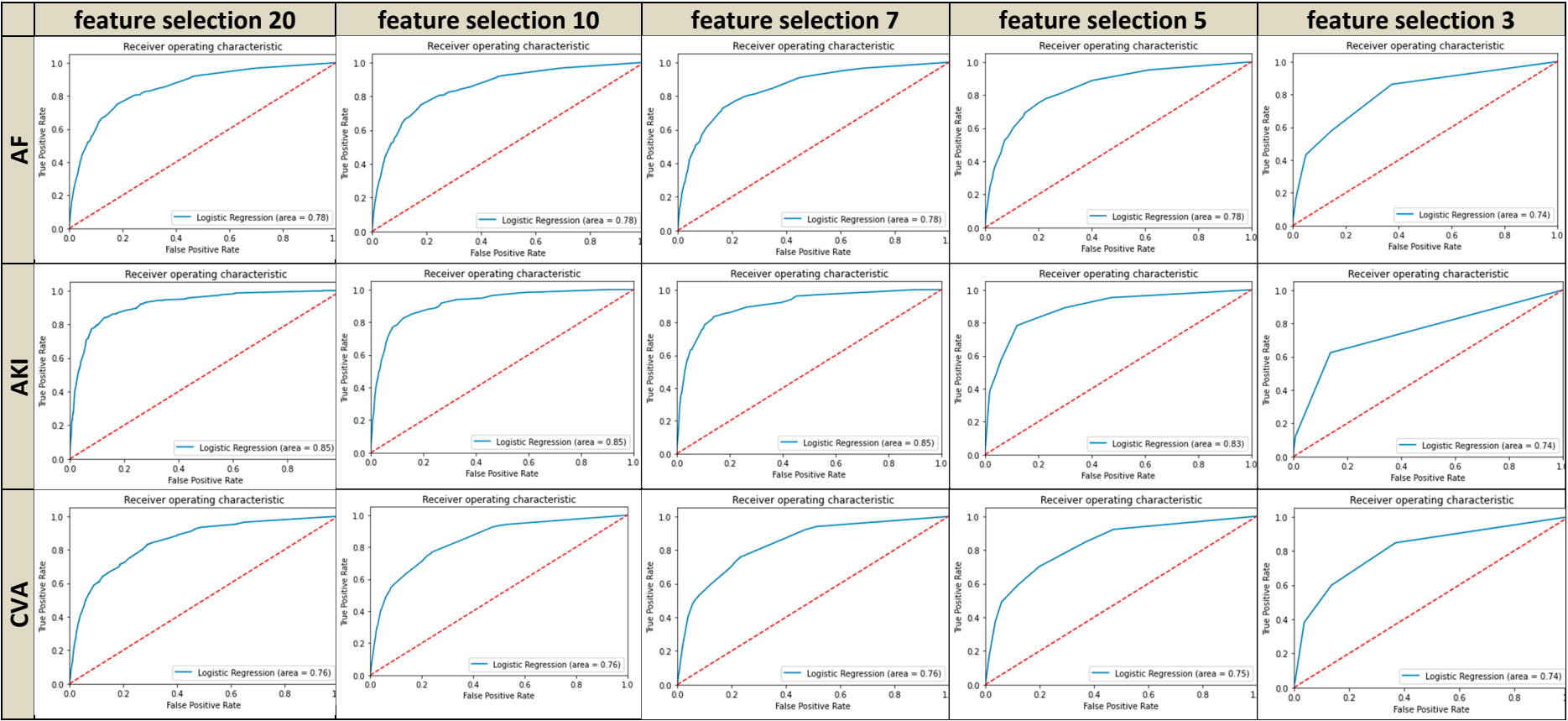
SOC= system organ class; PT= preferred term; PRR = proportional reporting ratio; ROR = reporting odd ratio; IC_{LB} = lower bound of information component 95% confidence interval; EBGM_{LB} = lower bound of empirical bayesian geometric mean 95% confidence interval

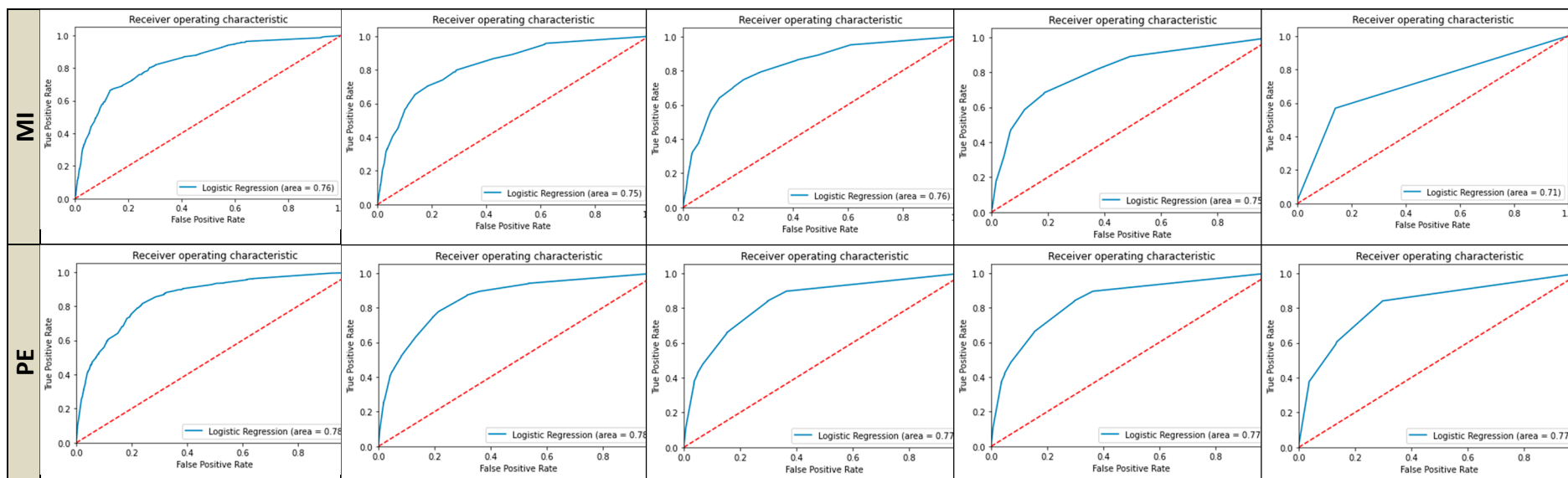
Table S8. Signals detected from serious adverse events after administration of Moderna (mRNA-1273).

| SOC | PT (n=37) | Count | PRR | ROR | IC _{LB} | EBGM _{LB} |
|--|---------------------------------------|-------|-------|--------------|------------------|--------------------|
| Cardiac disorders | Acute myocardial infarction | 358 | 10.24 | 10.27 | 0.19 | 1.21 |
| | Cardiomegaly | 190 | 7.07 | 7.08 | 0.09 | 1.15 |
| | Cardiac failure congestive | 265 | 4.93 | 4.94 | 0.10 | 1.15 |
| | Myocardial infarction | 500 | 4.54 | 4.55 | 0.16 | 1.17 |
| | Atrial fibrillation | 703 | 3.79 | 3.81 | 0.17 | 1.17 |
| | Cardiac arrest | 422 | 3.27 | 3.28 | 0.11 | 1.13 |
| | Myocarditis | 547 | 2.14 | 2.15 | 0.06 | 1.09 |
| General disorders and administration site conditions | Death | 3,673 | 4.31 | 4.41 | 0.27 | 1.23 |
| | General physical health deterioration | 257 | 3.98 | 3.99 | 0.08 | 1.13 |
| | Unevaluable event | 703 | 3.27 | 3.28 | 0.15 | 1.16 |
| | Condition aggravated | 1,727 | 2.46 | 2.48 | 0.16 | 1.14 |
| | Chest pain | 1,894 | 2.02 | 2.04 | 0.12 | 1.12 |
| Infections and infestations | Vaccine breakthrough infection | 667 | 82.69 | 83.14 | 0.29 | 1.28 |
| | COVID-19 | 5,515 | 29.72 | 31.10 | 0.38 | 1.32 |
| | Asymptomatic COVID-19 | 159 | 29.57 | 29.60 | 0.11 | 1.18 |
| | COVID-19 pneumonia | 1,076 | 28.58 | 28.83 | 0.31 | 1.29 |
| | Appendicitis | 167 | 10.35 | 10.36 | 0.09 | 1.15 |
| | Urinary tract infection | 344 | 3.20 | 3.20 | 0.08 | 1.12 |
| | Pneumonia | 950 | 2.10 | 2.11 | 0.10 | 1.10 |
| Nervous system disorders | Cerebrovascular accident | 1,091 | 4.14 | 4.17 | 0.21 | 1.20 |
| | Unresponsive to stimuli | 491 | 2.34 | 2.35 | 0.07 | 1.10 |
| Psychiatric disorders | Mental status changes | 439 | 2.44 | 2.44 | 0.06 | 1.10 |
| Renal and urinary disorders | Acute kidney injury | 620 | 5.76 | 5.79 | 0.21 | 1.20 |
| Respiratory, thoracic and mediastinal disorders | Acute respiratory failure | 724 | 17.95 | 18.05 | 0.28 | 1.26 |
| | Lung opacity | 468 | 17.40 | 17.47 | 0.24 | 1.24 |
| | Chronic obstructive pulmonary disease | 171 | 10.60 | 10.61 | 0.09 | 1.16 |
| | Pulmonary embolism | 1,159 | 9.58 | 9.66 | 0.28 | 1.26 |
| | Atelectasis | 174 | 9.24 | 9.26 | 0.09 | 1.15 |
| | Hypoxia | 979 | 8.67 | 8.73 | 0.27 | 1.25 |
| | Lung infiltration | 318 | 5.91 | 5.93 | 0.14 | 1.17 |
| | Pulmonary thrombosis | 232 | 5.39 | 5.40 | 0.09 | 1.14 |
| | Pleural effusion | 281 | 4.75 | 4.76 | 0.11 | 1.15 |
| | Dyspnoea exertional | 329 | 3.71 | 3.72 | 0.10 | 1.13 |
| | Cough | 1,946 | 3.40 | 3.44 | 0.22 | 1.19 |
| | Dyspnoea | 4,710 | 2.40 | 2.46 | 0.19 | 1.16 |
| Vascular disorders | Deep vein thrombosis | 544 | 7.78 | 7.81 | 0.22 | 1.22 |
| | Thrombosis | 510 | 3.87 | 3.88 | 0.15 | 1.16 |

SOC= system organ class; PT= preferred term; PRR = proportional reporting ratio; ROR = reporting odd ratio; IC_{LB} = lower bound of information component 95% confidence interval; EBGM_{LB} = lower bound of empirical bayesian geometric mean 95% confidence interval

Table S9. Area under the receiver operating characteristic curve (AUROC) with various numbers of selected features in major signals of AEFIs.





(days).