

Supplementary Table 1. The adverse events and MedDRA code used in the study.

Adverse event	MedDRA code
ILD – narrow terms	SMQ code: 20000042 (including MedDRA code: 10000001, 10000686, 10001028, 10001713, 10001714, 10001881, 10001889, 10001890, 10001891, 10001892, 10001893, 10001895, 10004067, 10004068, 10004941, 10004942, 10006448, 10007701, 10008832, 10009164, 10011495, 10014574, 10014952, 10014957, 10014962, 10015887, 10016221, 10016222, 10016640, 10016641, 10016649, 10016656, 10016659, 10016660, 10019107, 10020463, 10021225, 10021240, 10022611, 10022612, 10022617, 10022618, 10022619, 10025088, 10025089, 10025102, 10025103, 10026724, 10026725, 10026816, 10026819, 10028397, 10028398, 10029888, 10031486, 10032390, 10032439, 10032500, 10033523, 10035698, 10035715, 10035716, 10035742, 10035743, 10035750, 10035751, 10035754, 10035755, 10036028, 10036383, 10036805, 10037316, 10037317, 10037383, 10037384, 10037411, 10037413, 10037416, 10037429, 10037431, 10037457, 10037754, 10037758, 10037765, 10038718, 10042390, 10045622, 10045623, 10047130, 10047263, 10048016, 10048594, 10049202, 10050343, 10050354, 10050385, 10051211, 10052235, 10052832, 10052833, 10052835, 10052836, 10057237, 10058824, 10059809, 10060779, 10060902, 10061473, 10061924, 10062997, 10063725, 10066090, 10066153, 10066393, 10066394, 10066544, 10066725, 10066726, 10066728, 10066732, 10067445, 10067761, 10068186, 10068805, 10069406, 10070790, 10070831, 10070852, 10072879, 10072880, 10073344, 10073657, 10074889, 10076515, 10076522, 10077942, 10078117, 10078268, 10078788, 10080547, 10080701, 10081792, 10081849, 10081920, 10081988, 10082452, 10082588, 10082838, 10082999, 10083303, 10084211, 10084305, 10084309, 10084872, 10085058, 10085188, 10085189, 10085190, 10085191, 10085345, 10085352, 10085413, 10085517, 10085536, 10085628, 10085668, 10085686, 10086041, 10086072, 10086117, 10086122, 10086597, 10086598, 10086601, 10086926, 10086935, 10087294)
ILD – broad terms	SMQ code: 20000042 (including MedDRA code: 10000036, 10001052, 10001407, 10001408, 10001409, 10001410, 10003083, 10004795, 10006020, 10006449, 10006455, 10006456, 10006463, 10008427, 10009235, 10010187, 10010864, 10010865, 10010886, 10011496, 10013493, 10014956, 10018620, 10020119, 10021241, 10021242, 10023500, 10023601, 10023602, 10023688, 10024265, 10024266, 10024267, 10024268, 10024269, 10024270, 10024271, 10024272, 10024273, 10024274, 10025041, 10025104, 10025105, 10025106, 10025109, 10025117, 10028890, 10033569, 10034461, 10034462, 10034463, 10035008, 10035745, 10035753, 10036024, 10036025, 10036026, 10036027, 10037313, 10037314, 10037370, 10037382, 10037391, 10037392, 10037393, 10037396, 10037399, 10037412, 10037430, 10038689, 10038691, 10039081, 10039485, 10039486, 10039490, 10040579, 10042607, 10042786, 10042787, 10042809, 10042810, 10042811, 10042839, 10042954, 10045969, 10045970, 10047888, 10047889, 10048667, 10049459, 10049462, 10051222, 10051604, 10051688, 10052795, 10053133, 10053135, 10054039, 10054078, 10054079, 10056218, 10057261, 10057481, 10061230, 10063420)

	10064691, 10064695, 10065256, 10065656, 10066396, 10066847, 10067200, 10067471, 10067472, 10068513, 10068801, 10069152, 10069351, 10069698, 10069924, 10069927, 10070890, 10071396, 10071397, 10071869, 10072579, 10072580, 10073584, 10074611, 10075185, 10075289, 10078247, 10078811, 10084764, 10085269, 10085895, 10086936, 10086984, 10086985, 10086986)
Myocarditis / pericarditis (PT)	10064539, 10011258, 10056261, 10075553, 10014961, 10081004, 10082606, 10028606, 10065218, 10065219, 10066857, 10028612, 10059026, 10064550, 10028615, 10047470, 10055036, 10079058, 10004050
Thrombosis and Thromboembolism	SMQ code: 20000081, 20000082, 20000083, 20000084 (including MedDRA code: 20000082, 20000083, 20000084, 10000891, 10000892, 10000893, 10000894, 10000895, 10000896, 10000897, 10000898, 10000899, 10000900, 10000901, 10000902, 10000903, 10000904, 10000905, 10000906, 10000907, 10000908, 10000909, 10000910, 10000911, 10000912, 10000913, 10000914, 10000915, 10000916, 10000917, 10000918, 10000919, 10000920, 10000921, 10000922, 10000923, 10000924, 10000925, 10000926, 10000927, 10000928, 10000929, 10000930, 10000931, 10001902, 10001903, 10002432, 10002475, 10002677, 10002678, 10002679, 10002698, 10002893, 10002897, 10002910, 10002927, 10002930, 10002933, 10002937, 10002939, 10002940, 10003078, 10003140, 10003147, 10003154, 10003155, 10003156, 10003157, 10003158, 10003159, 10003160, 10003161, 10003164, 10003166, 10003178, 10003179, 10003180, 10003181, 10003182, 10003183, 10003195, 10003604, 10003606, 10003607, 10003608, 10003609, 10003610, 10003611, 10003612, 10003613, 10003614, 10003617, 10003723, 10003724, 10003873, 10004084, 10005183, 10005184, 10006071, 10006894, 10007643, 10007681, 10007684, 10007688, 10007691, 10007692, 10007693, 10007694, 10007971, 10008023, 10008080, 10008088, 10008089, 10008090, 10008091, 10008092, 10008108, 10008109, 10008133, 10008207, 10008213, 10011077, 10011084, 10011086, 10011090, 10011091, 10011098, 10011100, 10011101, 10011103, 10011104, 10011108, 10011166, 10012545, 10012990, 10014497, 10014499, 10014500, 10014501, 10014502, 10014503, 10014504, 10014505, 10014506, 10014509, 10014510, 10014513, 10014514, 10014515, 10014516, 10014517, 10014519, 10014520, 10014525, 10014526, 10014528, 10014529, 10014530, 10014531, 10014532, 10014533, 10014534, 10014535, 10014536, 10014538, 10014539, 10014648, 10016425, 10016428, 10016431, 10016432, 10016433, 10016453, 10019250, 10019635, 10019636, 10021337, 10021338, 10021339, 10021340, 10021400, 10021758, 10021763, 10021922, 10022463, 10022561, 10023027, 10024242, 10027394, 10027395, 10027396, 10027397, 10027524, 10027577, 10027579, 10027581, 10028595, 10028596, 10028597, 10028598, 10028599, 10028602, 10028870, 10029506, 10029975, 10029991, 10029992, 10029993, 10029994, 10029995, 10029996, 10029997, 10029998, 10029999, 10030000, 10030001, 10030003, 10030006, 10030008, 10030272, 10031672, 10032467, 10032904, 10033697, 10034087, 10034571, 10035002, 10036167, 10036231, 10036348, 10036349, 10036350, 10036357, 10036358, 10036359, 10036480, 10036511, 10036512, 10036513, 10037340, 10037562, 10037563, 10037690, 10037721, 10038376, 10038380, 10038822, 10038826, 10038827,

10038828, 10038831, 10039009, 10039365, 10040717, 10040730, 10042332, 10042333, 10042334, 10043211, 10043562, 10043565, 10043566, 10043567, 10043611, 10043612, 10043613, 10043614, 10043616, 10043617, 10043618, 10043620, 10043622, 10043624, 10043636, 10043637, 10043645, 10043646, 10043648, 10043821, 10043829, 10044373, 10044374, 10044375, 10044390, 10044391, 10044401, 10044405, 10044675, 10044699, 10046183, 10047532, 10048726, 10048790, 10048818, 10048963, 10048964, 10048965, 10048966, 10048988, 10049052, 10049065, 10049196, 10049440, 10049456, 10049533, 10049768, 10049845, 10049846, 10049847, 10049887, 10050277, 10050329, 10050339, 10050427, 10050592, 10051034, 10051078, 10051198, 10051592, 10051991, 10052019, 10052086, 10052244, 10052318, 10052475, 10052514, 10052515, 10052516, 10052517, 10052597, 10052714, 10052908, 10052949, 10052989, 10053003, 10053091, 10053092, 10053261, 10053350, 10053492, 10053493, 10053558, 10053620, 10053633, 10053660, 10053976, 10054156, 10054366, 10055221, 10055755, 10056382, 10056418, 10057368, 10057468, 10057490, 10057491, 10057492, 10057493, 10057518, 10057519, 10057525, 10057543, 10057544, 10057545, 10057546, 10057547, 10057548, 10057549, 10057550, 10057551, 10057552, 10057560, 10057569, 10057617, 10057702, 10057777, 10057787, 10057794, 10058069, 10058072, 10058144, 10058224, 10058475, 10058729, 10058731, 10058842, 10058903, 10058904, 10059135, 10059137, 10059613, 10059726, 10059869, 10060840, 10060848, 10061169, 10061256, 10061340, 10061651, 10061655, 10061657, 10061659, 10061751, 10062363, 10062585, 10062599, 10063025, 10063093, 10063172, 10063177, 10063518, 10063544, 10063731, 10063751, 10064345, 10064346, 10064347, 10064348, 10064601, 10064812, 10064958, 10065006, 10065009, 10065031, 10065384, 10065418, 10065557, 10065560, 10065608, 10066102, 10066286, 10066287, 10066341, 10066546, 10066581, 10066592, 10066640, 10066641, 10066645, 10066673, 10066719, 10067167, 10067273, 10067651, 10067676, 10067744, 10067748, 10067814, 10067825, 10068035, 10068109, 10068176, 10068312, 10068365, 10068503, 10068538, 10068677, 10068803, 10068903, 10069020, 10069035, 10069036, 10069037, 10069038, 10069379, 10069694, 10069695, 10069696, 10069697, 10071026, 10071111, 10071260, 10071261, 10071316, 10071550, 10071642, 10072121, 10072560, 10072561, 10072562, 10072564, 10072567, 10072639, 10072760, 10072761, 10072893, 10072896, 10073197, 10073529, 10074092, 10074318, 10074321, 10074337, 10074574, 10074575, 10074576, 10074577, 10074578, 10074600, 10074717, 10075162, 10075476, 10075505, 10076225, 10076604, 10076842, 10076895, 10077137, 10077765, 10077766, 10077772, 10077777, 10077778, 10078066, 10078067, 10078201, 10078269, 10078522, 10078523, 10078636, 10078867, 10078871, 10079262, 10079263, 10079264, 10079265, 10079266, 10079267, 10079573, 10079735, 10079739, 10079988, 10079989, 10080843, 10081144, 10081360, 10081560, 10081731, 10081893, 10082470, 10082522, 10082523, 10083408, 10083692, 10083693, 10083694, 10083695, 10083696, 10083697, 10083698, 10083699, 10083700, 10083701, 10083702, 10083703, 10083828, 10083829, 10083830, 10083831, 10083832, 10084343, 10084482, 10084483, 10084484, 10084485, 10084486, 10084487,

10084488, 10084489, 10084490, 10084702, 10084836, 10084843, 10084868, 10085044, 10085250, 10085346, 10085489, 10085490, 10085540, 10085541, 10085583, 10085584, 10085649, 10085715, 10085779, 10085987, 10086272, 10086367, 10086376, 10086395, 10086467, 10086560, 10086596, 10086829, 10087337, 10000374, 10000980, 10001108, 10001111, 10002438, 10002475, 10002661, 10002817, 10003004, 10003098, 10003192, 10003198, 10006053, 10006147, 10006538, 10008034, 10008082, 10008116, 10008117, 10008118, 10008119, 10008120, 10008121, 10008132, 10008133, 10008134, 10008135, 10008136, 10008137, 10008189, 10008190, 10008191, 10008196, 10008197, 10008198, 10008199, 10008200, 10008201, 10008202, 10008203, 10008204, 10009161, 10009667, 10010018, 10010053, 10010217, 10010785, 10010786, 10011091, 10011108, 10011693, 10012108, 10012126, 10012769, 10013033, 10013034, 10013048, 10013203, 10013429, 10013441, 10013442, 10013443, 10013597, 10013880, 10014498, 10014499, 10014501, 10014516, 10014517, 10014525, 10014651, 10015756, 10015757, 10016743, 10016813, 10017381, 10018968, 10019005, 10019013, 10019016, 10019023, 10019465, 10019466, 10019467, 10019468, 10019469, 10019470, 10019471, 10019472, 10019473, 10019527, 10019612, 10019679, 10019680, 10020566, 10020620, 10021173, 10021754, 10021755, 10021756, 10021757, 10021759, 10021761, 10021762, 10021764, 10022103, 10022104, 10022589, 10022590, 10022656, 10022657, 10023029, 10023030, 10023987, 10024097, 10024108, 10024116, 10024131, 10027394, 10027399, 10027400, 10027401, 10027403, 10027578, 10027580, 10027925, 10027926, 10027927, 10027928, 10027929, 10027930, 10027931, 10027932, 10027933, 10027934, 10027935, 10028877, 10030002, 10030003, 10030004, 10030936, 10031494, 10032086, 10032087, 10032117, 10032442, 10032749, 10033802, 10033814, 10033826, 10033885, 10033892, 10033893, 10033985, 10035092, 10036198, 10036199, 10036204, 10036228, 10036810, 10037713, 10037714, 10037715, 10037716, 10037717, 10037718, 10037719, 10038470, 10038471, 10039146, 10039154, 10039161, 10040621, 10041413, 10041648, 10042244, 10042942, 10043337, 10043385, 10043530, 10043540, 10043541, 10043565, 10043566, 10043567, 10043568, 10043576, 10043601, 10043602, 10043603, 10043604, 10043607, 10043609, 10043610, 10043615, 10043619, 10043622, 10043623, 10043626, 10043627, 10043628, 10043634, 10043647, 10043742, 10044381, 10044399, 10045149, 10045168, 10045385, 10045388, 10045413, 10045652, 10046033, 10046181, 10046182, 10046220, 10047082, 10047083, 10047142, 10047182, 10047866, 10048333, 10048497, 10048609, 10048620, 10048632, 10048672, 10048715, 10048792, 10048863, 10049060, 10049071, 10049165, 10049166, 10049196, 10049229, 10049265, 10049584, 10049599, 10049600, 10049601, 10049680, 10049707, 10049768, 10049769, 10049824, 10049908, 10049909, 10049910, 10049936, 10049945, 10050045, 10050046, 10050329, 10050339, 10050358, 10050374, 10050375, 10050387, 10050549, 10050550, 10051149, 10051172, 10051175, 10051269, 10051404, 10051601, 10051742, 10051902, 10051913, 10052081, 10052085, 10052090, 10052173, 10052253, 10052255, 10052256, 10052257, 10052259, 10052261, 10052709, 10052715, 10052906, 10053182, 10053351, 10053375, 10053601, 10053994, 10054132,

10054741, 10054750, 10055184, 10055278, 10055282, 10055284, 10055677, 10055678, 10055749, 10055750, 10057403, 10057493, 10057517, 10057534, 10057558, 10057613, 10057787, 10057802, 10057807, 10057822, 10058010, 10058296, 10058336, 10058408, 10058562, 10058568, 10058571, 10058707, 10058794, 10058944, 10058966, 10058977, 10058978, 10059025, 10059054, 10059063, 10059336, 10059337, 10059613, 10059829, 10060478, 10060574, 10060772, 10060839, 10060956, 10061142, 10061169, 10061216, 10061407, 10061604, 10062108, 10062506, 10062546, 10062573, 10063176, 10063382, 10063492, 10063679, 10063682, 10063868, 10063919, 10063933, 10063934, 10064039, 10064201, 10064397, 10064610, 10064620, 10064685, 10064961, 10065012, 10065013, 10065323, 10065335, 10065489, 10065496, 10065680, 10065780, 10065794, 10066055, 10066059, 10066087, 10066552, 10066553, 10066591, 10066616, 10066772, 10066856, 10067048, 10067052, 10067114, 10067130, 10067167, 10067347, 10067649, 10067650, 10067740, 10067794, 10067816, 10068067, 10068070, 10068187, 10068239, 10068256, 10068401, 10068535, 10068538, 10068543, 10068628, 10068644, 10068803, 10068826, 10068903, 10069036, 10069208, 10069729, 10069922, 10070527, 10070649, 10070671, 10070754, 10070761, 10070828, 10071043, 10071110, 10071171, 10071340, 10071341, 10071550, 10071652, 10072154, 10072226, 10072240, 10072241, 10072242, 10072243, 10072244, 10072245, 10072799, 10072917, 10072967, 10073625, 10073734, 10073735, 10073886, 10074127, 10074205, 10074398, 10074422, 10074494, 10074515, 10074583, 10074601, 10074896, 10074897, 10075178, 10075442, 10075805, 10075806, 10075968, 10076026, 10076145, 10076190, 10076303, 10076304, 10076490, 10076611, 10076654, 10076714, 10076725, 10076763, 10076838, 10076839, 10076843, 10076844, 10076845, 10076855, 10076856, 10076857, 10076858, 10076859, 10076895, 10076919, 10076920, 10076929, 10076930, 10076933, 10076934, 10077022, 10077143, 10077147, 10077148, 10077149, 10077212, 10077273, 10077353, 10077410, 10077455, 10077456, 10077479, 10077480, 10077765, 10077766, 10077777, 10077778, 10077791, 10078041, 10078043, 10078063, 10078065, 10078311, 10078352, 10078675, 10078895, 10079251, 10079523, 10079902, 10079929, 10080067, 10080069, 10080295, 10080673, 10080794, 10080795, 10080796, 10080803, 10080814, 10080924, 10081076, 10081763, 10081994, 10081996, 10082031, 10082513, 10082519, 10083006, 10083066, 10083087, 10083561, 10083562, 10083668, 10083687, 10083691, 10083786, 10083804, 10083812, 10083825, 10083826, 10083827, 10083985, 10084072, 10084091, 10084095, 10084352, 10084735, 10084858, 10084916, 10085213, 10085325, 10085458, 10085669, 10085687, 10085689, 10085691, 10085715, 10085987, 10086070, 10086158, 10086161, 10086162, 10086278, 10086367, 10086412, 10086441, 10086442, 10086443, 10086549, 10086554, 10087113, 10087222, 10081074, 10081075, 10081584, 10087402, 10087403, 10087404, 10081070, 10000853, 10000970, 10003880, 10006536, 10006537, 10007830, 10007934, 10007972, 10007976, 10008138, 10009092, 10009111, 10012089, 10012090, 10012091, 10012092, 10012093, 10012094, 10012096, 10012097, 10012098, 10012107, 10013013, 10013877, 10013878, 10013879, 10014507, 10014508, 10014511, 10014512, 10014521,

	10014522, 10014537, 10019713, 10019714, 10021182, 10021760, 10021923, 10021924, 10022776, 10022823, 10023103, 10023237, 10024105, 10024607, 10024945, 10026926, 10026927, 10026928, 10026929, 10026930, 10026931, 10027402, 10027403, 10028239, 10029661, 10029914, 10029915, 10029916, 10029917, 10029918, 10029919, 10029925, 10030004, 10030009, 10032333, 10032334, 10032335, 10032336, 10032337, 10032338, 10032395, 10032438, 10033035, 10033036, 10034191, 10034272, 10034324, 10034883, 10034885, 10034886, 10034887, 10034893, 10034894, 10034901, 10034904, 10036206, 10036299, 10036300, 10036425, 10037300, 10037301, 10037302, 10037377, 10037378, 10037380, 10037409, 10037410, 10037421, 10037436, 10037437, 10037438, 10037458, 10037459, 10037611, 10038547, 10038548, 10038906, 10038907, 10038908, 10039366, 10039369, 10041659, 10042545, 10042554, 10042555, 10042556, 10042557, 10042558, 10042559, 10042560, 10042561, 10042562, 10042563, 10042564, 10042567, 10042568, 10042569, 10042570, 10042642, 10042793, 10043570, 10043571, 10043572, 10043573, 10043574, 10043575, 10043577, 10043578, 10043579, 10043580, 10043581, 10043582, 10043583, 10043584, 10043585, 10043586, 10043587, 10043588, 10043589, 10043590, 10043591, 10043592, 10043595, 10043596, 10043605, 10043606, 10043621, 10043625, 10043629, 10043630, 10043631, 10043632, 10043633, 10043635, 10043638, 10043639, 10043640, 10043641, 10043642, 10043643, 10044457, 10047188, 10047193, 10047195, 10047196, 10047207, 10047209, 10047216, 10047217, 10047225, 10047226, 10047230, 10047232, 10047233, 10047247, 10047248, 10047249, 10047250, 10047251, 10047252, 10047253, 10047254, 10047255, 10047256, 10047257, 10047258, 10048541, 10048589, 10048591, 10048874, 10048932, 10049446, 10049903, 10049915, 10049916, 10049917, 10049918, 10050071, 10050216, 10050224, 10050225, 10050593, 10050902, 10051031, 10051043, 10051055, 10051475, 10051567, 10052090, 10052471, 10052612, 10052698, 10052720, 10052721, 10052964, 10053377, 10053378, 10053379, 10053380, 10053381, 10053382, 10053383, 10053384, 10053681, 10053702, 10054346, 10054751, 10056293, 10056513, 10056966, 10057256, 10057337, 10057725, 10058707, 10058987, 10058988, 10058989, 10058990, 10058991, 10058992, 10059254, 10059519, 10059520, 10060905, 10061251, 10061407, 10061408, 10062173, 10062175, 10062589, 10063363, 10063389, 10063675, 10063679, 10063682, 10063909, 10063919, 10064602, 10065052, 10065139, 10065142, 10065380, 10066426, 10066529, 10066661, 10066738, 10066881, 10066899, 10067030, 10067270, 10067740, 10068046, 10068122, 10068389, 10068479, 10068605, 10068606, 10068690, 10069131, 10069133, 10069388, 10069727, 10070911, 10070915, 10071739, 10072059, 10073531, 10073708, 10073979, 10074196, 10074349, 10074397, 10074658, 10074664, 10075428, 10075429, 10075430, 10075439, 10075440, 10076226, 10076285, 10076835, 10076837, 10076841, 10077623, 10077826, 10077829, 10077852, 10078810, 10078908, 10079164, 10079209, 10080372, 10081850, 10081877, 10082030, 10082134, 10082138, 10082853, 10082854, 10083037, 10083093, 10083103, 10083106, 10083184, 10084100, 10084102, 10084157, 10084397, 10084527, 10086210, 10086463,
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	10087020, 10087021, 10087022, 10087023, 10087102, 10087181, 10087208,
Anaphylaxis	10002198, 10002199, 10002218, 10042930, 10042931, 10069526, 10002394, 10002395, 10002424, 10002425, 10002426, 10018257, 10018259, 10020198, 10046744, 10001734, 10001718, 10001719, 10001738
Thrombocytopenia	10043551, 10043554, 10043555, 10043560, 10043569, 10039884, 10024922, 10035528, 10035529, 10035545, 10038213, 10043546, 10074667, 10021243, 10021245, 10023095, 10051064, 10043552, 10043558
Generalized convulsion	10010916, 10010917, 10018079, 10010914, 10010904, 10010906, 10010922, 10039906, 10039910, 10016731, 10016735, 10039910, 10009234, 10010915, 10010923, 10010926, 10016733, 10003628, 10071377
Guillain Barré Syndrome	10018767, 10018766, 10042812, 10000813, 10067898, 10033803, 10049567
Aseptic meningitis	10003458, 10027201, 10029669, 10057724, 10047469, 10046236, 10027260, 10027262, 10028263, 10028273, 10027250, 10027220, 10027213, 10027214, 10027222, 10027215, 10027229, 10027211, 10011253
Encephalitis / Encephalomyelitis / Acute disseminated encephalomyelitis	10014581, 10014601, 10014588, 10056198, 10014602, 10054373, 10028524, 10028526, 10028527, 10000709
Bell's Palsy	10004223, 10033559, 10016060, 10016062, 10033808
Vaccine associated enhanced disease	10085491, 10085001

Supplementary Table 2. The types and WHODrug recode number codes used in the study.

Type of drugs	WHODrug record number
COVID-19 vaccines	
Tozinameran	15268625001, 15268625002, 15268625003, 15268625004, 15268625005, 15268625006, 15268625007, 15268625008, 15268625009
Vaxzevria	15268603001, 15268603002, 15268603003, 15268603004, 15268603005, 15268603006, 15268603007, 15268603008, 15268603009, 15268603010, 15268603012, 15268603013, 15268603014
Elasomeran	15268604001, 15268604002, 15268604003, 15268604004, 15268604005, 15268604006, 15268604007, 15268604008
Ad26.CO2.S	15268640001, 15268640002, 15268640003, 15268640004, 15268640005, 15268640006, 15268640007
Gam-COVID-Vac	15268619005, 15268684002, 15268619007, 15268620004
NVX-CoV2373	15268611001, 15268611002, 15268611003, 15268611004, 15268611005
GBP510	15268665003
Cancer therapy	
Bleomycin	001839xxxxx (94)
Gemcitabine	012157xxxxx (326)
Erlotinib	016114xxxxx (93)
Gefitinib	015601xxxxx (92)
Panitumumab	017773xxxxx (5)
Cetuximab	014905xxxxx (5)
Everolimus	015069xxxxx (61)
Temsirolimus	017165xxxxx (6)
Sirolimus	014591xxxxx (35)
Nivolumab	078729xxxxx (4)
Pembrolizumab	083428xxxxx (6)
Avelumab	089186xxxxx (3)
Durvalumab	087572xxxxx (4)
Ipilimumab	057456xxxxx (7)
Rheumatology therapy	
methotrexate	001138xxxxx (416)
Leflunomide	014148xxxxx (214)
Infliximab	014456xxxxx (24)
Etanercept	014906xxxxx (25)
Adalimumab	016129xxxxx (40)
Tocilizumab	017591xxxxx (11)
Rituximab	014025xxxxx (60)
Anti-infection	
Nitrofurantoin	000244xxxxx (230)
Daptomycin	016772xxxxx (57)
Interferon	005968xxxxx (4)
Cardiology drugs	
Amiodarone	001331xxxxx (293)
Bepridil	007889xxxxx (11)
Lovastatin	008967xxxxx (249)
Simvastatin	008481xxxxx (946)
Pravastatin	008804xxxxx (381)
Atorvastatin	013261xxxxx (1225)
Fluvastatin	012245xxxxx (146)

Rosuvastatin	015886xxxxx (999)
Cerivastatin	013413xxxxx (28)

The bracket () indicates the numbers of drugs.

Supplementary Table 3. Analysis strategies

Analysis types	Case	Non-case	Vaccine of interest	Other vaccines	Comment
Primary analysis	ILD narrow terms	Non-ILD	COVID-19 vaccines	The other vaccines	
Subgroup analysis	ILD narrow terms	Non-ILD	COVID-19 vaccines	The other vaccines	
1. Age	ILD narrow terms	Non-ILD	COVID-19 vaccines	The other vaccines	<65 and ≥65 years
2. Gender	ILD narrow terms	Non-ILD	COVID-19 vaccines	The other vaccines	Male and female
3. Region	ILD narrow terms	Non-ILD	COVID-19 vaccines	The other vaccines	Western Pacific region and the other regions
Sensitivity analysis					
1. ICSRs reported as suspected, concomitant, and interaction drugs	ILD narrow terms	Non-ILD	COVID-19 vaccines	The other vaccines	Diverse AE definition
2. Extended the ILD definition (broad search)	ILD narrow+broad	Non-ILD	COVID-19 vaccines	The other vaccines	Diverse AE definition (Information bias)
3. ICSRs excluding reports included either cancer therapy or rheumatology drugs or anti-infection agents, cardiology drugs [†]	ILD narrow terms	Non-ILD	COVID-19 vaccines	The other vaccines	Drug competition bias
4. ICSRs excluding reports included COVID-19 vaccine AESIs	ILD narrow terms	Non-ILD	COVID-19 vaccines	The other vaccines	Event competition bias
5. Restricted to serious AE reports	ILD narrow terms	Non-ILD	COVID-19 vaccines	The other vaccines	Weber effect
6. ICSRs before August 6, 2021	ILD narrow terms	Non-ILD	COVID-19 vaccines	The other vaccines	Notoriety bias
7. Definition of influenza vaccine as positive control	ILD narrow terms	Non-ILD	COVID-19 vaccines	Influenza vaccine	Positive control

[†]Cancer therapy: bleomycin; gemcitabine; Epidermal Growth Factor Receptor (EGFR)-targeted agent (erlotinib, gefitinib, panitumumab, cetuximab); mammalian target of rapamycin (MTOR)-inhibitor (everolimus, temsirolimus, sirolimus); immune checkpoint inhibitor (nivolumab, pembrolizumab, avelumab, durvalumab, ipilimumab), rheumatology drugs: methotrexate; leflunomide, biological disease-modifying anti-rheumatic drugs (DMARDs) (tumor necrosis factor (TNF) agent (infliximab, etanercept, adalimumab), tocilizumab, rituximab), anti-infection agents (nitrofurantoin, daptomycin, interferon), cardiology drugs (amiodarone, bepridil, statin (lovastatin, simvastatin, pravastatin, atorvastatin, fluvastatin, rosuvastatin, cerivastatin))

ILD, interstitial lung disease; COVID-19, coronavirus disease 2019; AESI, adverse event of special interest

Supplementary Table 4. Characteristics of interstitial lung disease (ILD) by COVID-19 vaccines, influenza vaccines, and others.

	COVID-19 vaccines		Influenza vaccines		Others	
	N	%	N	%	N	%
Reported quarter (Q)						
2020.4Q (Dec. 13, 2020~Dec. 31, 2020)	0	(0.0)	0	(0.0)	0	(0.0)
2021.1Q (Jan. 1, 2021 ~ Mar. 31, 2021)	46	(7.4)	3	(8.8)	1	(3.0)
2021.2Q (Apr. 1, 2021 ~ Jun. 30, 2021)	100	(16.0)	5	(14.7)	1	(3.0)
2021.3Q (Jul. 1, 2021 ~ Sep. 30, 2021)	107	(17.1)	8	(23.5)	2	(6.1)
2021.4Q (Oct. 1, 2021 ~ Dec. 31, 2021)	97	(15.5)	3	(8.8)	6	(18.2)
2022.1Q (Jan. 1, 2022 ~ Mar. 31, 2022)	100	(16.0)	4	(11.8)	1	(3.0)
2022.2Q (Apr. 1, 2022 ~ Jun. 30, 2022)	70	(11.2)	4	(11.8)	8	(24.2)
2022.3Q (Jul. 1, 2022 ~ Sep. 30, 2022)	44	(7.0)				
2022.4Q (Oct. 1, 2022 ~ Dec. 31, 2022)	51	(8.2)	4	(11.8)	13	(39.4)
2023.1Q (Jan. 1, 2023 ~ Jan. 26, 2023)	11	(1.8)	3	(8.8)	1	(3.0)
Age groups						
0~27 days			2	(5.9)		
28 days to 23 months	2	(0.3)	3	(8.8)	21	(63.6)
2~11 years			1	(2.9)	3	(9.1)
12~17 years	4	(0.6)				
18~44 years	91	(14.5)	1	(2.9)	1	(3.0)
45~64 years	182	(29.1)	6	(17.7)	2	(6.1)
65~74 years	134	(21.4)	11	(32.4)	4	(12.1)
≥ 75 years	213	(34.0)	10	(29.4)	2	(6.1)
Sex						
Male	325	(51.9)	18	(52.9)	20	(60.6)
Female	301	(48.1)	16	(47.1)	13	(39.4)
Report type						
Spontaneous	578	(92.3)	29	(85.3)	23	(69.7)
Report from study	41	(6.6)	5	(14.7)	10	(30.3)
Other	7	(1.1)				
Serious						
Yes	578	(92.3)	31	(91.2)	29	(87.9)
Seriousness						
Death	107	(17.1)	7	(20.6)	5	(15.2)
Life threatening	96	(15.3)	3	(8.8)		
Caused/Prolonged Hospitalization	260	(41.5)	14	(41.2)	16	(48.5)
Disabling/Incapacitating	13	(2.1)	1	(2.9)		
Congenital anomaly/Birth defect						
Other	102	(16.3)	6	(17.7)	8	(24.2)
Region						
African	4	(0.6)				
Americas	42	(6.7)	9	(26.5)	5	(15.2)
South-East Asia	5	(0.8)			1	(3.0)
European	543	(86.7)	20	(58.8)	25	(75.8)
Eastern Mediterranean	7	(1.1)	1	(2.9)		
Western Pacific	25	(4.0)	4	(11.8)	2	(6.1)
Notifier type						
Physician	493	(78.8)	24	(70.6)	21	(63.6)
Pharmacist	45	(7.2)	3	(8.8)	3	(9.1)
Other Health Professional	88	(14.1)	7	(20.6)	9	(27.3)
Time to onset						

Mean±SD	33.5±61.7	17.1±24.7	40.9±128.7
Median (Q1-Q3)	8 (1-36)	5 (2-23)	6 (1-21)

SD; standard deviation

COVID-19 vaccines contained Tozinameran, Elasmomeran, Vaxzevira, Ad26.COVS.2.S, Gam-COVID-Vac, and NVX-CoV2373. Influenza vaccines were defined using Anatomical Therapeutic Chemical (ATC) classification; J07BB.

Supplementary Table 5. The list of reported adverse events (AEs) in narrow and broad terms (>2 report).

No.	Narrow terms			Narrow + broad terms		
	MedDRA terms	Count	%	MedDRA terms	Count	%
1	Pneumonitis	134	19.7	Pneumonitis	134	12.3
2	Interstitial lung disease	70	10.3	Acute respiratory distress syndrome	128	11.7
3	Interstitial pneumonia	46	6.8	Sarcoidosis	83	7.6
4	Pulmonitis	45	6.6	Interstitial lung disease	70	6.4
5	Lung infiltration	37	5.4	Interstitial pneumonia	46	4.2
6	Interstitial pneumonitis	32	4.7	Pulmonitis	45	4.1
7	Bronchiolitis	30	4.4	Lung infiltration	37	3.4
8	Pneumonia interstitial	30	4.4	Interstitial pneumonitis	32	2.9
9	Ground glass opacity in thoracic CT	27	4.0	Pneumonia interstitial	30	2.7
10	Pulmonary fibrosis	19	2.8	Bronchiolitis	30	2.7
11	Lung inflammation	18	2.7	Cryptogenic organising pneumonia	29	2.7
12	Eosinophilic pneumonia	17	2.5	ARDS	27	2.5
13	Lung opacity	16	2.4	Ground glass opacity in thoracic CT	27	2.5
14	Eosinophilic granulomatosis with polyangiitis	16	2.4	Pulmonary alveolar haemorrhage	21	1.9
15	Pulmonary infiltration	15	2.2	Pulmonary fibrosis	19	1.7
16	Alveolitis	13	1.9	Lung inflammation	18	1.6
17	Hypersensitivity pneumonitis	12	1.8	Eosinophilic pneumonia	17	1.6
18	Bilateral pulmonary infiltrates	10	1.5	Eosinophilic granulomatosis with polyangiitis	16	1.5
19	Exacerbation of idiopathic pulmonary fibrosis	10	1.5	Lung opacity	16	1.5
20	Churg Strauss syndrome	9	1.3	Pulmonary infiltration	15	1.4
21	Lung fibrosis	8	1.2	Adult respiratory stress syndrome	14	1.3
22	Alveolitis allergic	7	1.0	Alveolitis	13	1.2
23	Idiopathic pulmonary fibrosis	6	0.9	Granulomatosis with polyangiitis	13	1.2
24	Pulmonary vasculitis	6	0.9	Hypersensitivity pneumonitis	12	1.1
25	Acute respiratory distress syndrome	6	0.9	Organizing pneumonia	11	1.0
26	ARDS	5	0.7	A.R.D.S.	11	1.0
27	Pneumonia eosinophilic	4	0.6	Antisynthetase syndrome	10	0.9
28	Interstitial pneumonia aggravated	4	0.6	Bilateral pulmonary infiltrates	10	0.9
29	Diffuse alveolar damage	4	0.6	Exacerbation of idiopathic pulmonary fibrosis	10	0.9
30	Rheumatoid arthritis-associated interstitial lung disease	4	0.6	Churg Strauss syndrome	9	0.8
31	Ground glass opacity on chest X-ray	4	0.6	Polyarteritis nodosa	9	0.8
32	Fibrosis lung	3	0.4	Lung fibrosis	8	0.7
33	Lymphocytic alveolitis	3	0.4	Cryptogenic organizing	8	0.7

				pneumonia		
34	Lung infiltration NOS	3	0.4	Pulmonary sarcoidosis	7	0.6
35	Interstitial lung fibrosis	3	0.4	Goodpasture's syndrome	7	0.6
36	Acute interstitial pneumonitis	3	0.4	Organising pneumonia	7	0.6
37	Pulmonary alveolar haemorrhage	3	0.4	Wegener's granulomatosis	7	0.6
38				Alveolitis allergic	7	0.6
39				Loefgren syndrome	6	0.5
40				Pulmonary vasculitis	6	0.5
41				Idiopathic pulmonary fibrosis	6	0.5
42				Adult respiratory distress syndrome	6	0.5
43				Rheumatoid arthritis-associated interstitial lung disease	4	0.4
44				Ground glass opacity on chest X-ray	4	0.4
45				Interstitial pneumonia aggravated	4	0.4
46				Diffuse alveolar damage	4	0.4
47				Granulomatous polyangiitis	4	0.4
48				Pneumonia eosinophilic	4	0.4
49				Syndrome respiratory distress adult	4	0.4
50				Periarteritis nodosa	4	0.4
51				Lung injury	3	0.3
52				Lung infiltration NOS	3	0.3
53				Wegeners granulomatosis	3	0.3
54				Pulmonary renal syndrome	3	0.3
55				Acute interstitial pneumonitis	3	0.3
56				Pulmonary granuloma	3	0.3
57				Pulmonary alveolar hemorrhage	3	0.3
58				Interstitial lung fibrosis	3	0.3
59				Fibrosis lung	3	0.3
60				Lymphocytic alveolitis	3	0.3
61				Lung transplant rejection	3	0.3

* only included in narrow and broad terms

MedDRA, medical dictionary for regulatory activities

Supplementary Table 6. Reporting odds ratio (ROR) of subgroups analyses in primary analysis

Type of analysis	ILD-cases	Non-cases	ROR (95% CI)
Subgroup analysis 1, age			
Age<65 (case=315, non-case=3,150)			
The other vaccines	36 (11.4)	339 (10.8)	
COVID-19 vaccines	268 (85.1)	2,447 (77.7)	0.94 (0.65–1.35)
mRNA COVID-19 vaccines	198 (62.9)	1,611 (51.1)	1.16 (0.80–1.68)
Tozinameran	158 (52.2)	1,328 (48.1)	1.12 (0.77–1.64)
Elasomeran	40 (13.2)	272 (9.8)	1.39 (0.86–2.23)
Viral vector COVID-19 vaccines	70 (22.2)	837 (26.6)	0.79 (0.52–1.20)
Vaxzevria	64 (21.1)	676 (24.5)	0.89 (0.58–1.37)
Gam-COVID-Vac	0 (0.0)	1 (0.0)	NC
Ad26.COV2.S	5 (1.7)	147 (5.3)	0.32 (0.12–0.83)
Protein-based COVID-19 vaccines	0 (0.0)	1 (0.0)	NC
NVX-CoV2373	0 (0.0)	1 (0.0)	NC
Others	11 (3.5)	362 (11.5)	0.29 (0.14–0.57)
Age≥65 (case=364, non-case=3,640)			
The other vaccines	17 (4.7)	120 (3.3)	
COVID-19 vaccines	347 (95.3)	3,520 (96.7)	0.70(0.41–1.17)
mRNA COVID-19 vaccines	250 (68.7)	2,301 (63.2)	0.77(0.45–1.30)
Tozinameran	215 (65.2)	1,954 (59.7)	0.78(0.46–1.32)
Elasomeran	33 (10.0)	339 (10.4)	0.69(0.37–1.28)
Viral vector COVID-19 vaccines	67 (18.4)	881 (24.2)	0.54(0.31–0.95)
Vaxzevria	62 (18.8)	785 (24.0)	0.56(0.32–0.99)
Gam-COVID-Vac	0 (0.0)	1 (0.0)	NC
Ad26.COV2.S	3 (0.9)	73 (2.2)	0.29(0.08–1.02)
Protein-based COVID-19 vaccines	0 (0.0)	2 (0.1)	NC
NVX-CoV2373	0 (0.0)	2 (0.1)	NC
Others	30 (8.2)	336 (9.2)	0.63(0.34–1.18)
Subgroup analysis 2, gender			
Male (case=356, non-case=3,230)			
The other vaccines	31 (8.7)	254 (7.1)	
COVID-19 vaccines	325 (91.3)	3,306 (92.9)	0.81(0.55–1.19)
mRNA COVID-19 vaccines	235 (66.0)	2,009 (56.4)	0.96(0.65–1.43)
Tozinameran	194 (57.9)	1,697 (54.2)	0.94(0.63–1.40)
Elasomeran	40 (11.9)	304 (9.7)	1.08(0.66–1.77)
Viral vector COVID-19 vaccines	71 (19.9)	898 (25.2)	0.65(0.42–1.01)
Vaxzevria	67 (20.0)	739 (23.6)	0.74(0.47–1.16)
Gam-COVID-Vac	0 (0.0)	2 (0.1)	NC
Ad26.COV2.S	3 (0.9)	137 (4.4)	0.18(0.05–0.60)
Protein-based COVID-19 vaccines	0 (0.0)	0 (0.0)	NC
NVX-CoV2373	0 (0.0)	0 (0.0)	NC
Others	19 (5.3)	399 (11.2)	0.39(0.22–0.71)
Female (case=305, non-case=3,050)			
The other vaccines	22 (6.8)	205 (6.4)	-
COVID-19 vaccines	301 (93.2)	3,025 (93.7)	0.93(0.59–1.46)
mRNA COVID-19 vaccines	213 (65.9)	1,903 (58.9)	1.04(0.66–1.66)
Tozinameran	22 (7.4)	205 (7.1)	1.05(0.66–1.68)
Elasomeran	179 (60.1)	1,585 (54.6)	1.00(0.57–1.77)
Viral vector COVID-19 vaccines	66 (20.4)	820 (25.4)	0.75(0.45–1.24)
Vaxzevria	59 (19.8)	722 (24.9)	0.76(0.46–1.27)
Gam-COVID-Vac	0 (0.0)	0 (0.0)	NC

Ad26.COVS2.S	5 (1.7)	83 (2.9)	0.56(0.21–1.53)
Protein-based COVID-19 vaccines	0 (0.0)	3 (0.1)	<.001 (<.001->999.9)
NVX-CoV2373	0 (0.0)	3 (0.1)	<.001 (<.001->999.9)
Others	22 (6.8)	299 (9.3)	0.69(0.37–1.27)
Subgroup analysis 3, region			
Western Pacific Region (case=30, non-case=933)			
The other vaccines	5 (16.7)	73 (7.8)	
COVID-19 vaccines	25 (83.3)	860 (92.2)	0.42(0.16–1.14)
mRNA COVID-19 vaccines	14 (46.7)	359 (38.5)	0.57(0.20–1.63)
Tozinameran	13 (48.2)	316 (45.6)	0.60(0.21–1.74)
Elasomeran	1 (3.7)	43 (6.2)	0.34(0.04–3.00)
Viral vector COVID-19 vaccines	10 (33.3)	267 (28.6)	0.55(0.18–1.65)
Vaxzevria	8 (29.6)	219 (31.6)	0.53(0.17–1.68)
Gam-COVID-Vac	0 (0.0)	0 (0.0)	NC
Ad26.COVS2.S	0 (0.0)	42 (6.1)	NC
Protein-based COVID-19 vaccines	0 (0.0)	0 (0.0)	NC
NVX-CoV2373	0 (0.0)	0 (0.0)	NC
Others	1 (3.3)	234 (25.1)	0.06(0.01–0.54)
The other regions (case=649, non-case=5,857)			
The other vaccines	48 (7.4)	386 (6.6)	
COVID-19 vaccines	601 (92.6)	5,471 (93.4)	0.88(0.65–1.21)
mRNA COVID-19 vaccines	434 (66.9)	3,553 (60.7)	0.98(0.72–1.35)
Tozinameran	360 (59.4)	2,966 (55.5)	0.98(0.71–1.34)
Elasomeran	72 (11.9)	568 (10.6)	1.02(0.69–1.50)
Viral vector COVID-19 vaccines	127 (19.6)	1,451 (24.8)	0.70(0.50–1.00)
Vaxzevria	118 (19.5)	1,242 (23.2)	0.76(0.54–1.09)
Gam-COVID-Vac	0 (0.0)	2 (0.0)	NC
Ad26.COVS2.S	8 (1.3)	178 (3.3)	0.36(0.17–0.78)
Protein-based COVID-19 vaccines	0 (0.0)	3 (0.1)	NC
NVX-CoV2373	0 (0.0)	3 (0.1)	NC
Others	40 (6.2)	464 (7.9)	0.69(0.45–1.08)

COVID-19, coronavirus disease 2019; ILD, interstitial lung disease; ROR, reporting odds ratio; NC, not calculated

Supplementary Table 7. Reporting odds ratio (ROR) of sensitivity analyses

Type of analysis	ILD cases	Non-cases	ROR (95% CI)
Sensitivity analysis 1 (case=644, non-case=6,440)			
The other vaccines	53 (7.8)	449 (6.6)	
COVID-19 vaccines	626 (92.2)	6,338 (93.4)	0.84(0.62–1.13)
mRNA COVID-19 vaccines	448 (66.0)	3,863 (56.9)	0.98(0.73–1.33)
Tozinameran	373 (58.9)	3,265 (54.3)	0.97(0.71–1.31)
Elasomeran	73 (11.5)	582 (9.7)	1.06(0.73–1.55)
Viral vector COVID-19 vaccines	137 (20.2)	1,743 (25.7)	0.67(0.48–0.93)
Vaxzevria	126 (19.9)	1,469 (24.4)	0.73(0.52–1.02)
Gam-COVID-Vac	0 (0.0)	4 (0.1)	NC
Ad26.COV2.S	8 (1.3)	241 (4.0)	0.28(0.13–0.60)
Protein-based COVID-19 vaccines	0 (0.0)	2 (0.0)	NC
NVX-CoV2373	0 (0.0)	2 (0.0)	NC
Others	41 (6.0)	730 (10.8)	0.48(0.31–0.73)
Sensitivity analysis 2 (case=548, non-case=5,480)			
The other vaccines	67 (6.1)	521 (4.8)	
COVID-19 vaccines	1,026 (93.9)	10,409 (95.2)	0.77(0.59–1.00)
mRNA COVID-19 vaccines	704 (64.4)	6,340 (58.0)	0.86(0.66–1.13)
Tozinameran	604 (60.0)	5,326 (55.0)	0.88(0.68–1.15)
Elasomeran	95 (9.4)	983 (10.1)	0.75(0.54–1.05)
Viral vector COVID-19 vaccines	251 (23.0)	2,906 (26.6)	0.67(0.51–0.89)
Vaxzevria	221 (22.0)	2,483 (25.6)	0.69(0.52–0.92)
Gam-COVID-Vac	1 (0.1)	4 (0.0)	1.94(0.21–17.65)
Ad26.COV2.S	19 (1.9)	372 (3.8)	0.40(0.24–0.67)
Protein-based COVID-19 vaccines	0 (0.0)	3 (0.0)	NC
NVX-CoV2373	0 (0.0)	3 (0.0)	NC
Others	71 (6.5)	1,160 (10.6)	0.48(0.34–0.68)
Sensitivity analysis 3 (case=567, non-case=6,131)			
The other vaccines	41 (7.1)	416 (7.2)	
COVID-19 vaccines	538 (92.9)	5,374 (92.8)	1.02(0.73–1.42)
mRNA COVID-19 vaccines	391 (67.5)	3,264 (56.4)	1.22(0.87–1.70)
Tozinameran	327 (59.9)	2,746 (53.5)	1.21(0.86–1.70)
Elasomeran	62 (11.4)	498 (9.7)	1.26(0.83–1.91)
Viral vector COVID-19 vaccines	117 (20.2)	1,497 (25.9)	0.79(0.55–1.15)
Vaxzevria	109 (20.0)	1,283 (25.0)	0.86(0.59–1.26)
Gam-COVID-Vac	0 (0.0)	3 (0.1)	NC
Ad26.COV2.S	7 (1.3)	186 (3.6)	0.38(0.17–0.87)
Protein-based COVID-19 vaccines	0 (0.0)	1 (0.0)	NC
NVX-CoV2373	0 (0.0)	1 (0.0)	NC
Others	30 (5.2)	612 (10.6)	0.50(0.31–0.81)
Sensitivity analysis 4 (case=584, non-case=5,840)			
The other vaccines	43 (7.2)	414 (6.9)	
COVID-19 vaccines	554 (92.8)	5,556 (93.1)	0.96(0.69–1.33)
mRNA COVID-19 vaccines	398 (66.7)	3,461 (58.0)	1.11(0.80–1.54)
Tozinameran	330 (59.4)	2,883 (54.5)	1.10(0.79–1.54)
Elasomeran	66 (11.9)	559 (10.6)	1.14(0.76–1.70)
Viral vector COVID-19 vaccines	119 (19.9)	1,474 (24.7)	0.78(0.54–1.12)
Vaxzevria	110 (19.8)	1,241 (23.5)	0.85(0.59–1.24)
Gam-COVID-Vac	0 (0.0)	1 (0.0)	<.001 (<.001->999.9)
Ad26.COV2.S	7 (1.3)	193 (3.7)	0.35(0.15–0.79)
Protein-based COVID-19 vaccines	0 (0.0)	0 (0.0)	-

NVX-CoV2373	0 (0.0)	0 (0.0)	-
Others	37 (6.2)	621 (10.4)	0.57(0.36–0.91)
Sensitivity analysis 5 (case=591, non-case=5,910)			
The other vaccines	47 (7.5)	344 (5.5)	
COVID-19 vaccines	578 (92.5)	5,906 (94.5)	0.72(0.52–0.98)
mRNA COVID-19 vaccines	417 (66.7)	4,078 (65.3)	0.75(0.54–1.03)
Tozinameran	347 (59.4)	3,582 (60.5)	0.71(0.51–0.98)
Elasomeran	68 (11.6)	477 (8.1)	1.04(0.70–1.55)
Viral vector COVID-19 vaccines	125 (20.0)	1,558 (24.9)	0.59(0.41–0.84)
Vaxzevria	115 (19.7)	1,323 (22.3)	0.64(0.44–0.91)
Gam-COVID-Vac	0 (0.0)	0 (0.0)	NC
Ad26.COV2.S	7 (1.2)	194 (3.3)	0.26(0.12–0.60)
Protein-based COVID-19 vaccines	0 (0.0)	1 (0.0)	NC
NVX-CoV2373	0 (0.0)	1 (0.0)	NC
Others	36 (5.8)	269 (4.3)	0.98(0.62–1.56)
Sensitivity analysis 6 (case=197, non-case=1,970)			
The other vaccines	10 (5.1)	76 (3.9)	
COVID-19 vaccines	187 (94.9)	1,894 (96.1)	0.75(0.38–1.48)
mRNA COVID-19 vaccines	123 (62.4)	1,164 (59.1)	0.80(0.41–1.59)
Tozinameran	109 (56.8)	1,025 (56.8)	0.81(0.41–1.61)
Elasomeran	14 (7.3)	139 (7.7)	0.77(0.32–1.81)
Viral vector COVID-19 vaccines	59 (30.0)	567 (28.8)	0.79(0.39–1.61)
Vaxzevria	57 (29.7)	554 (30.7)	0.78(0.38–1.60)
Gam-COVID-Vac	0 (0.0)	1 (0.1)	NC
Ad26.COV2.S	2 (1.0)	11 (0.6)	1.38(0.27–7.16)
Protein-based COVID-19 vaccines	0 (0.0)	0 (0.0)	NC
NVX-CoV2373	0 (0.0)	0 (0.0)	NC
Others	5 (2.5)	163 (8.3)	0.23(0.08–0.71)
Sensitivity analysis 7 (case=606, non-case=6,060)			
Influenza vaccines	20 (3.3)	89 (1.5)	Reference
COVID-19 vaccines	586 (96.7)	5,971 (98.5)	0.44(0.27–0.71)
mRNA COVID-19 vaccines	448 (73.9)	4,071 (67.2)	0.49(0.30–0.80)
Tozinameran	373 (62.2)	3,376 (56.5)	0.49(0.30–0.81)
Elasomeran	73 (12.2)	669 (11.2)	0.49(0.28–0.84)
Viral vector COVID-19 vaccines	137 (22.6)	1,893 (31.2)	0.32(0.19–0.54)
Vaxzevria	126 (21.0)	1,544 (25.8)	0.36(0.22–0.61)
Gam-COVID-Vac	0 (0.0)	6 (0.1)	NC
Ad26.COV2.S	8 (1.3)	292 (4.9)	0.12(0.05–0.29)
Protein-based COVID-19 vaccines	0 (0.0)	1 (0.0)	NC
NVX-CoV2373	0 (0.0)	1 (0.0)	NC
Others	1 (0.2)	6 (0.1)	0.74(0.09–6.51)

COVID-19, coronavirus disease 2019; ILD, interstitial lung disease; ROR, reporting odds ratio; NC, not calculated
sensitivity analysis 1: included ICSRs of COVID-19 vaccines as suspected, concomitant, and interaction;
sensitivity analysis 2: defined ILD including MedDRA SMQ narrow and broad terms (broad search); sensitivity
analysis 4: excluded ICSRs that included drugs known to cause drug-induced ILD; sensitivity analysis 3: excluded
reports containing adverse event special interest (AESI) of COVID-19 vaccines; sensitivity analysis 5: restricted to
ICSRs reported serious AE following COVID-19 vaccination; sensitivity analysis 6: containing ICSRs with a
reporting date before August 6, 2021; sensitivity analysis 7: compared the COVID-19 vaccines with the influenza
vaccines as a positive control.

Supplementary Table 8. Characteristic of interstitial lung disease (ILD) and non-ILD of sensitivity analysis 7 (compared COVID-19 vaccines with influenza vaccines)

	ILD cases (N=606)		Non-cases (N=6,060)		p-value
	N	%	N	%	
Reported quarter (Q)					0.0216
2020.4Q (Dec. 13, 2020~Dec. 31, 2020)	0	(0.0)	10	(0.2)	
2021.1Q (Jan. 1, 2021 ~ Mar. 31, 2021)	47	(7.8)	645	(10.6)	
2021.2Q (Apr. 1, 2021 ~ Jun. 30, 2021)	100	(16.5)	1,152	(19.0)	
2021.3Q (Jul. 1, 2021 ~ Sep. 30, 2021)	110	(18.2)	847	(14.0)	
2021.4Q (Oct. 1, 2021 ~ Dec. 31, 2021)	96	(15.8)	887	(14.6)	
2022.1Q (Jan. 1, 2022 ~ Mar. 31, 2022)	98	(16.2)	843	(13.9)	
2022.2Q (Apr. 1, 2022 ~ Jun. 30, 2022)	66	(10.9)	773	(12.8)	
2022.3Q (Jul. 1, 2022 ~ Sep. 30, 2022)	39	(6.4)	408	(6.7)	
2022.4Q (Oct. 1, 2022 ~ Dec. 31, 2022)	40	(6.6)	426	(7.0)	
2023.1Q (Jan. 1, 2023 ~ Jan. 26, 2023)	10	(1.7)	69	(1.1)	
Age groups					1
0~27 days	2	(0.3)	20	(0.3)	
28 days to 23 months	4	(0.7)	40	(0.7)	
2~11 years	1	(0.2)	10	(0.2)	
12~17 years	4	(0.7)	40	(0.7)	
18~44 years	90	(14.9)	900	(14.9)	
45~64 years	176	(29.0)	1,760	(29.0)	
65~74 years	127	(21.0)	1,270	(21.0)	
≥ 75 years	202	(33.3)	2,020	(33.3)	
Sex					1
Male	318	(52.5)	3,180	(52.5)	
Female	288	(47.5)	2,880	(47.5)	
Report type					<.0001
Spontaneous	567	(93.6)	5,651	(93.3)	
Report from study	33	(5.5)	182	(3.0)	
Other	6	(1.0)	226	(3.7)	
Not available to sender (unknown)	0	(0.0)	1	(0.0)	
Vaccines type					
COVID-19 vaccines	586	(96.7)	5,971	(98.5)	0.0007
Tozinameran	376	(62.1)	3,437	(56.7)	0.0115
Elasomeran	78	(12.9)	715	(11.8)	0.4368
Vaxzevria	129	(21.3)	1,589	(26.2)	0.0081
Ad26.COVS.2	0	(0.0)	6	(0.1)	0.4384
Gam-COVID-Vac	8	(1.3)	298	(4.9)	<.0001
NVX-CoV2373	0	(0.0)	1	(0.0)	1
Influenza vaccines	34	(5.6)	133	(2.2)	<.0001
Pneumococcal vaccines	5	(0.8)	9	(0.2)	0.0005
Drug known to cause ILD included in the ICSRst					
Cancer therapy	15	(2.5)	2	(0.0)	<.0001
Rheumatology therapy	21	(3.5)	25	(0.4)	<.0001
Anti-infection agent	3	(0.5)	6	(0.1)	0.0414
Cardiology drugs	55	(9.1)	244	(4.0)	<.0001
Serious					<.0001
Yes	561	(92.6)	2,311	(38.1)	
Seriousness					<.0001
Death	267	(4.4)	98	(16.2)	

Life threatening	128 (2.1)	95 (15.7)	
Caused/Prolonged Hospitalization	576 (9.5)	254 (41.9)	
Disabling/Incapacitating	88 (1.5)	13 (2.2)	
Congenital anomaly/Birth defect	1 (0.0)	0 (0.0)	
Other	1,251 (20.6)	101 (16.7)	
Region			<.0001
African	4 (0.7)	333 (5.5)	
Americas	32 (5.3)	507 (8.4)	
South-East Asia	4 (0.7)	124 (2.1)	
European	533 (88.0)	4,276 (70.6)	
Eastern Mediterranean	6 (1.0)	127 (2.1)	
Western Pacific	27 (4.5)	693 (11.4)	
Notifier type			<.0001
Physician	484 (79.9)	3,555 (58.7)	
Pharmacist	43 (7.1)	929 (15.3)	
Other Health Professional	79 (13.0)	1,576 (26.0)	
Time to onset (case=549, non-case=5,743)			0.2784
Mean±SD	32.5±59.4	29.6±58.7	
Median (Q1-Q3)	8 (2-36)	1 (0-18)	

ILD; interstitial lung disease, SD; standard deviation

[†] Cancer therapy: bleomycin; gemcitabine; Epidermal Growth Factor Receptor (EGFR)-targeted agent (erlotinib, gefitinib, panitumumab, cetuximab); mammalian target of rapamycin (MTOR)-inhibitor (everolimus, temsirolimus, sirolimus); immune checkpoint inhibitor (nivolumab, pembrolizumab, avelumab, durvalumab, ipilimumab), rheumatology drugs: methotrexate; leflunomide, biological disease-modifying anti-rheumatic drugs (DMARDs) (tumor necrosis factor (TNF) agent (infliximab, etanercept, adalimumab), tocilizumab, rituximab), anti-infection agents (nitrofurantoin, daptomycin, interferon), cardiology drugs (amiodarone, bepridil, statin (lovastatin, simvastatin, pravastatin, atorvastatin, fluvastatin, rosuvastatin, cerivastatin))

Supplementary Table 9. Reporting odds ratio (ROR) of subgroups analyses in sensitivity analysis 7

Type of analysis	ILD-cases	Non-cases	ROR (95% CI)
Subgroup analysis 1, age			
Age<65 (case=277, non-case=2,770)			
The other vaccines	9 (3.3)	33 (1.2)	
COVID-19 vaccines	268 (96.8)	2,737 (98.8)	0.36(0.17–0.76)
mRNA COVID-19 vaccines	198 (71.5)	1,783 (64.4)	0.41(0.19–0.86)
Tozinameran	1,460 (53.4)	158 (57.3)	0.40(0.19–0.84)
Elasomeran	308 (11.3)	40 (14.5)	0.48(0.21–1.07)
Viral vector COVID-19 vaccines	70 (25.3)	953 (34.4)	0.27(0.12–0.59)
Vaxzevria	743 (27.2)	64 (23.2)	0.32(0.15–0.69)
Gam-COVID-Vac	4 (0.2)	0 (0.0)	NC
Ad26.COV2.S	188 (6.9)	5 (1.8)	0.10(0.03–0.31)
Protein-based COVID-19 vaccines	0 (0.0)	0 (0.0)	NC
NVX-CoV2373	0 (0.0)	0 (0.0)	NC
Others	0 (0.0)	1 (0.0)	NC
Age≥65 (case=329, non-case=3,290)			
The other vaccines	11 (3.3)	56 (1.7)	
COVID-19 vaccines	318 (96.7)	3,234 (98.3)	0.50(0.26–0.97)
mRNA COVID-19 vaccines	250 (76.0)	2,288 (69.5)	0.56(0.29–1.08)
Tozinameran	215 (66.4)	1,916 (59.1)	0.57(0.30–1.11)
Elasomeran	33 (10.2)	361 (11.1)	0.47(0.22–0.97)
Viral vector COVID-19 vaccines	67 (20.4)	940 (28.6)	0.36(0.18–0.73)
Vaxzevria	62 (19.1)	801 (24.7)	0.39(0.20–0.79)
Gam-COVID-Vac	0 (0.0)	2 (0.1)	NC
Ad26.COV2.S	3 (0.9)	104 (3.2)	0.15(0.04–0.55)
Protein-based COVID-19 vaccines	0 (0.0)	1 (0.0)	NC
NVX-CoV2373	0 (0.0)	1 (0.0)	NC
Others	1 (0.3)	5 (0.2)	1.02(0.11–9.59)
Subgroup analysis 2, gender			
Male (case=318, non-case=3,180)			
The other vaccines	11 (3.5)	47 (1.5)	
COVID-19 vaccines	307 (96.5)	3,133 (98.5)	0.42(0.22–0.82)
mRNA COVID-19 vaccines	235 (73.9)	2,107 (66.3)	0.48(0.24–0.93)
Tozinameran	194 (61.6)	1,739 (55.4)	0.48(0.24–0.93)
Elasomeran	40 (12.7)	356 (11.3)	0.48(0.23–1.00)
Viral vector COVID-19 vaccines	71 (22.3)	1,026 (32.3)	0.30(0.15–0.60)
Vaxzevria	67 (21.3)	810 (25.8)	0.35(0.18–0.71)
Gam-COVID-Vac	0 (0.0)	4 (0.1)	NC
Ad26.COV2.S	3 (1.0)	182 (5.8)	0.07(0.02–0.26)
Protein-based COVID-19 vaccines	0 (0.0)	0 (0.0)	NC
NVX-CoV2373	0 (0.0)	0 (0.0)	NC
Others	1 (0.3)	0 (0.0)	NC
Female (case=288, non-case=2,880)			
The other vaccines	9 (3.1)	42 (1.5)	
COVID-19 vaccines	279 (96.9)	2,838 (98.5)	0.46(0.22–0.95)
mRNA COVID-19 vaccines	213 (74.0)	1,964 (68.2)	0.51(0.24–1.05)
Tozinameran	179 (62.8)	1,637 (57.7)	0.51(0.24–1.07)
Elasomeran	33 (11.6)	313 (11.0)	0.49(0.22–1.10)
Viral vector COVID-19 vaccines	66 (22.9)	867 (30.1)	0.36(0.17–0.76)
Vaxzevria	59 (20.7)	734 (25.9)	0.38(0.17–0.81)
Gam-COVID-Vac	0 (0.0)	2 (0.1)	NC

Ad26.COVS2.S	5 (1.8)	110 (3.9)	0.21(0.07–0.67)
Protein-based COVID-19 vaccines	0 (0.0)	1 (0.0)	NC
NVX-CoV2373	0 (0.0)	1 (0.0)	NC
Others	0 (0.0)	6 (0.2)	NC
Subgroup analysis 3, region			
Western Pacific Region (case=27, non-case=693)			
The other vaccines	3 (11.1)	17 (2.5)	
COVID-19 vaccines	24 (88.9)	676 (97.6)	0.20(0.06–0.73)
mRNA COVID-19 vaccines	14 (51.9)	376 (54.3)	0.21(0.06–0.80)
Tozinameran	13 (52.0)	330 (48.1)	0.22(0.06–0.86)
Elasomeran	1 (4.0)	46 (6.7)	0.12(0.01–1.27)
Viral vector COVID-19 vaccines	10 (37.0)	298 (43.0)	0.19(0.05–0.76)
Vaxzevria	8 (32.0)	240 (35.0)	0.19(0.05–0.78)
Gam-COVID-Vac	0 (0.0)	0 (0.0)	NC
Ad26.COVS2.S	0 (0.0)	52 (7.6)	NC
Protein-based COVID-19 vaccines	0 (0.0)	1 (0.1)	NC
NVX-CoV2373	0 (0.0)	1 (0.2)	NC
Others	0 (0.0)	1 (0.1)	NC
The other regions (case=579, non-case=5,367)			
The other vaccines	17 (2.9)	72 (1.3)	
COVID-19 vaccines	562 (97.1)	5,295 (98.7)	0.45(0.26–0.77)
mRNA COVID-19 vaccines	434 (75.0)	3,695 (68.9)	0.50(0.29–0.85)
Tozinameran	360 (62.6)	3,046 (57.6)	0.50(0.29–0.86)
Elasomeran	72 (12.5)	623 (11.8)	0.49(0.27–0.88)
Viral vector COVID-19 vaccines	127 (21.9)	1,595 (29.7)	0.34(0.19–0.59)
Vaxzevria	118 (20.5)	1,304 (24.7)	0.38(0.22–0.67)
Gam-COVID-Vac	0 (0.0)	6 (0.1)	NC
Ad26.COVS2.S	8 (1.4)	240 (4.5)	0.14(0.06–0.34)
Protein-based COVID-19 vaccines	0 (0.0)	0 (0.0)	NC
NVX-CoV2373	0 (0.0)	0 (0.0)	NC
Others	1 (0.2)	5 (0.1)	0.85(0.09–7.73)

COVID-19, coronavirus disease 2019; ILD, interstitial lung disease; ROR, reporting odds ratio; NC, not calculated