

Z.16025/02/2018-IMM-Part(1)
Government of India
Ministry of Health & Family Welfare
Immunization Division

Nirman Bhawan, New Delhi
Date: 13th April 2022

Causality assessment results of 161 reported Serious Adverse Events Following Immunization (AEFI) cases following COVID-19 vaccination approved by National AEFI Committee on 05th April 2022.

The Immunization Division, MoHFW has taken several steps to strengthen the national AEFI surveillance system for COVID-19 vaccinations. Considering the importance and critical nature of the task, steps were taken to include medical specialists, cardiologists, neurologists, pulmonary medicine specialists, and obstetrician-gynecologist as members of the causality assessment sub-committee at the national level. A Special Group has been framed to conduct causality assessment of AEFIs following COVID-19 vaccination. The results of the causality assessment done by this Special Group is discussed in the national AEFI committee meeting for final approval.

The results of the causality assessment for 161 cases completed on 05th April 2022 after thorough review, deliberation, and approval by the National AEFI Committee is given in the annexure (anonymized line list of the causality assessment done by the National AEFI Committee).

25 out of 161 cases for which Causality assessment has been done were found to have **consistent causal association to vaccination**. Of these 25 cases, 21 cases were vaccine product-related reaction and 4 cases were immunization anxiety-related reaction. 89 cases have an inconsistent causal association to immunization (**coincidental - not linked to vaccination**), including 58 death cases. 25 cases were in the indeterminate category including 05 death cases. There were 22 cases in the unclassifiable category including 21 death cases.

Vaccine product-related reactions are expected reactions that can be attributed to vaccination based on current scientific evidence. Examples of such reactions are allergic reactions and anaphylaxis, etc.

Indeterminate reactions are reactions which have occurred soon after vaccination but there is no definitive evidence in current literature or clinical trial data that this event could have been caused due to the vaccine. Further observations, analysis, and studies are required.

Unclassifiable events are events which have been investigated but there is not enough evidence for assigning a diagnosis due to missing crucial information. When this relevant information becomes available, the case may be reconsidered for causality assessment.

Coincidental events are events that are reported following immunization but for which a clear cause other than vaccination is found on investigation.

Overall, the benefits of vaccination are overwhelmingly greater than the small risk of harm. However, as a measure of utmost precaution, all emerging signals of harm are being constantly tracked and reviewed periodically.

CAUSALITY CLASSIFICATION OF 161 AEFI CASES APPROVED BY THE NATIONAL AEFI COMMITTEE ON 05-04-2022 (NEW DELHI)

A1 - VACCINE PRODUCT RELATED REACTION

A2 - VACCINE QUALITY DEFECT RELATED REACTION

A3 - IMMUNIZATION ERROR RELATED REACTION

A4 - IMMUNIZATION ANXIETY RELATED REACTION

B1 - TEMPORAL RELATIONSHIP IS CONSISTENT BUT THERE IS INSUFFICIENT DEFINITIVE EVIDENCE FOR VACCINE CAUSING EVENT

B2 - REVIEWING FACTORS RESULT IN CONFLICTING TRENDS OF CONSISTENCY AND INCONSISTENCY WITH CAUSAL ASSOCIATION TO IMMUNIZATION

C - COINCIDENTAL - UNDERLYING OR EMERGING CONDITION(S), OR CONDITIONS CAUSED BY EXPOSURE TO SOMETHING OTHER THAN VACCINE

D - UNCLASSIFIABLE

S. NO.	NATIONAL ID	YEAR	AGE (IN YEARS)	SEX	REASON FOR REPORTING/ OUTCOME	DATE OF VACCINATION (DD/MM/YYYY)	VACCINE	DIAGNOSIS	CLASSIFICATION* BY NATIONAL AEFI COMMITTEE	DATE OF APPROVAL BY NATIONAL AEFI COMMITTEE
1	IND(CO-AEFI)GUDEV21001	2021	24	MALE	DEATH	21/01/2021	COVISHIELD	UNEXPLAINED DEATH	D	05/04/2022
2	IND(CO-AEFI)MHTHN21004	2021	60	FEMALE	SEVERE AND RECOVERED	23/01/2021	COVISHIELD	CHIKUNGUNYA FEVER	C	05/04/2022
3	IND(CO-AEFI)HAPKL21003	2021	42	FEMALE	SEVERE AND RECOVERED	25/01/2021	COVISHIELD	BLURRING OF VISION	D	05/04/2022
4	IND(CO-AEFI)APPKM21002	2021	22	MALE	DEATH	24/02/2021	COVISHIELD	UROSEPSIS WITH MULTI ORGAN FAILURE	C	05/04/2022
5	IND(CO-AEFI)RJCTG21003	2021	64	MALE	DEATH	12/03/2021	COVISHIELD	SUDDEN CARDIAC DEATH WITH POST MORTEM SUGGESTIVE OF MYOCARDIAL INFARCTION	C	05/04/2022
6	IND(CO-AEFI)KETHR21002	2021	82	FEMALE	DEATH	15/03/2021	COVISHIELD	SUDDEN CARDIAC DEATH	C	05/04/2022
7	IND(CO-AEFI)HAPKL21004	2021	70	MALE	DEATH	19/03/2021	COVISHIELD	SUDDEN CARDIAC DEATH WITH UNDERLYING CORONARY ARTERY DISEASE	C	05/04/2022
8	IND(CO-AEFI)UADDN21002	2021	52	MALE	DEATH	16-03-2021	COVISHIELD	UNEXPLAINED DEATH	D	05/04/2022
9	IND(CO-AEFI)JHRMG21001	2021	55	MALE	HOSPITALIZED AND RECOVERED	14/03/2021	COVISHIELD	ACCELERATED HYPERTENSION WITH STROKE	C	05/04/2022
10	IND(CO-AEFI)CGBLM21002	2021	60	FEMALE	DEATH	25-03-2021	COVISHIELD	SUDDEN CARDIAC DEATH IN A KNOWN CASE OF HYPERTENSION	C	05/04/2022
11	IND(CO-AEFI)CGKNK21004	2021	61	MALE	HOSPITALIZED AND RECOVERED	12/03/2021	COVISHIELD	CEREBROVASCULAR ACCIDENT	C	05/04/2022
12	IND(CO-AEFI)CGKNK21003	2021	87	FEMALE	DEATH	13/03/2021	COVISHIELD	SEPTICEMIA	C	05/04/2022
13	IND(CO-AEFI)KEKNU21003	2021	44	FEMALE	HOSPITALIZED AND RECOVERED	04/02/2021	COVISHIELD	ACUTE THROMBOSIS SYNDROME INVOLVING PULMONARY THROMBO EMBOLISM AND INFERIOR VENA CAVA THROMBOSIS WITH NORMAL PLATELETS	B1	05/04/2022
14	IND(CO-AEFI)GOGON21011	2021	64	FEMALE	HOSPITALIZED AND RECOVERED	30/03/2021	COVISHIELD	THROMBOTIC STROKE WITH UNDERLYING DIABETES MELLITUS, HYPERTENSION AND PAST STROKE	C	05/04/2022
15	IND(CO-AEFI)BIARR21001	2021	68	MALE	HOSPITALIZED AND RECOVERED	25/03/2021	COVISHIELD	PNEUMONIA AND LEG ULCER WITH SEPSIS	C	05/04/2022
16	IND(CO-AEFI)JHBOK21001	2021	56	FEMALE	DEATH	13/04/2021	COVISHIELD	SUDDEN CARDIAC DEATH IN A KNOWN CASE OF HYPERTENSION AND HYPOTHYROIDISM	C	05/04/2022
17	IND(CO-AEFI)KEPTM21006	2021	70	FEMALE	DEATH	16-04-2021	COVISHIELD	SUDDEN CARDIAC DEATH WITH UNDERLYING CORONARY HEART DISEASE	C	05/04/2022
18	IND(CO-AEFI)KEAPZ21021	2021	60	FEMALE	HOSPITALIZED AND RECOVERED	09/04/2021	COVISHIELD	VOMITING AND DIARRHEA	A1	05/04/2022
19	IND(CO-AEFI)MHBMC21050	2021	53	MALE	DEATH	21-04-2021	COVISHIELD	UNEXPLAINED DEATH	D	05/04/2022
20	IND(CO-AEFI)TRTRW21016	2021	82	MALE	HOSPITALIZED AND RECOVERED	26-03-2021	COVISHIELD	VOMITING	A1	05/04/2022
21	IND(CO-AEFI)KABMP21021	2021	50	MALE	HOSPITALIZED AND RECOVERED	18-04-2021	COVISHIELD	VIRAL PNEUMONIA (RTPCR NEGATIVE)	C	05/04/2022
22	IND(CO-AEFI)WBNDG21002	2021	71	MALE	HOSPITALIZED AND RECOVERED	01/04/2021	COVISHIELD	SEPTIC ENCEPHALOPATHY	C	05/04/2022
23	IND(CO-AEFI)MPDMH21003	2021	47	MALE	HOSPITALIZED AND RECOVERED	01/04/2021	COVISHIELD	ENTERIC FEVER	C	05/04/2022
24	IND(CO-AEFI)MPSNI21009	2021	72	FEMALE	DEATH	17/03/2021	COVISHIELD	SUDDEN CARDIAC DEATH WITH UNDERLYING DIABETES MELLITUS AND HYPERTENSION	C	05/04/2022

CAUSALITY CLASSIFICATION OF 161 AEFI CASES APPROVED BY THE NATIONAL AEFI COMMITTEE ON 05-04-2022 (NEW DELHI)

A1 - VACCINE PRODUCT RELATED REACTION

A2 - VACCINE QUALITY DEFECT RELATED REACTION

A3 - IMMUNIZATION ERROR RELATED REACTION

A4 - IMMUNIZATION ANXIETY RELATED REACTION

B1 - TEMPORAL RELATIONSHIP IS CONSISTENT BUT THERE IS INSUFFICIENT DEFINITIVE EVIDENCE FOR VACCINE CAUSING EVENT

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25	IND(CO-AEFI)UPBRL21012	2021	28	MALE	HOSPITALIZED AND RECOVERED	22/01/2021	COVISHIELD	POST COVID MULTI SYSTEM INFLAMMATORY SYNDROME	C	05/04/2022
26	IND(CO-AEFI)MHPLG21001	2021	56	FEMALE	SEVERE AND RECOVERED	26-02-2021	COVISHIELD	LICHEN PLANUS	B1	05/04/2022
27	IND(CO-AEFI)RJPR21006	2021	70	FEMALE	HOSPITALIZED AND RECOVERED	24-04-2021	COVAXIN	GENERALISED WEAKNESS AND MALAISE	A1	05/04/2022
28	IND(CO-AEFI)TSSYP21003	2021	56	MALE	DEATH	25-04-2021	COVISHIELD	SUDDEN CARDIAC DEATH IN A KNOWN CASE OF DIABETES AND OLD PULMONARY MDR TB	C	05/04/2022
29	IND(CO-AEFI)MHBMC21052	2021	59	MALE	HOSPITALIZED AND RECOVERED	13/03/2021	COVISHIELD	PTYRIASIS RUBRA PILARIS	C	05/04/2022
30	IND(CO-AEFI)GUGNR21005	2021	63	MALE	HOSPITALIZED AND RECOVERED	09/04/2021	COVISHIELD	GUILLAIN BARRE SYNDROME	B1	05/04/2022
31	MUDUMALA POLIREDDY	2021	60	MALE	DEATH	10/03/2021	COVISHIELD	SUDDEN CARDIAC DEATH WITH UNDERLYING DIABETES MELLITUS AND HYPERTENSION	C	05/04/2022
32	IND(CO-AEFI)GOGON21030	2021	69	FEMALE	DEATH	20/04/2021	COVISHIELD	SEVERE COVID-19 PNEUMONIA	C	05/04/2022
33	IND(CO-AEFI)MPJBP21003	2021	53	MALE	HOSPITALIZED AND RECOVERED	22-02-2021	COVISHIELD	COVID-19 PNEUMONIA	C	05/04/2022
34	IND(CO-AEFI)CHCHD21002	2021	53	FEMALE	HOSPITALIZED AND RECOVERED	13/04/2021	COVISHIELD	THROMBOCYTOPENIA	A1	05/04/2022
35	SHIKHA VERMA	2021	36	FEMALE	DEATH	14/05/2021	COVISHIELD	UNEXPLAINED DEATH	D	05/04/2022
36	IND(CO-AEFI)KEKOT21007	2021	84	MALE	DEATH	29/03/2021	COVISHIELD	SUDDEN CARDIAC DEATH WITH UNDERLYING CORONARY HEART DISEASE	C	05/04/2022
37	IND(CO-AEFI)GOGOS21015	2021	32	FEMALE	HOSPITALIZED AND RECOVERED	04/06/2021	COVISHIELD	LEFT LOWER LIMB DEEP VEIN THROMBOSIS	B2	05/04/2022
38	IND(CO-AEFI)HPSML21001	2021	48	MALE	HOSPITALIZED AND RECOVERED	05/05/2021	COVISHIELD	LEFT UPPER LIMB DEEP VEIN THROMBOSIS	B1	05/04/2022
39	IND(CO-AEFI)WBHRA21001	2021	54	MALE	HOSPITALIZED AND RECOVERED	03/02/2021	COVISHIELD	ACUTE KIDNEY INJURY IN A RENAL ALLOGRAFT RECIPIENT	C	05/04/2022
40	IND(CO-AEFI)ORPUR21004	2021	57	MALE	DEATH	16-06-2021	COVISHIELD	INTRACRANIAL HEMORRHAGE	C	05/04/2022
41	IND(CO-AEFI)RJBTP21003	2021	56	MALE	HOSPITALIZED AND RECOVERED	05/04/2021	COVISHIELD	RIGHT SIDED PNEUMOTHORAX IN A CHRONIC SMOKER WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE	C	05/04/2022
42	IND(CO-AEFI)MPUMR21001	2021	70	MALE	DEATH	24/04/2021	COVISHIELD	SUDDEN CARDIAC DEATH	C	05/04/2022
43	IND(CO-AEFI)UPMRD21009	2021	35	FEMALE	HOSPITALIZED AND RECOVERED	15/06/2021	COVISHIELD	ACUTE KIDNEY INJURY FOLLOWING GASTROENTERITIS	C	05/04/2022
44	IND(CO-AEFI)MPMRN21002	2021	28	MALE	DEATH	23/06/2021	COVISHIELD	LEFT FRONTAL GLIOMA	C	05/04/2022
45	IND(CO-AEFI)UPAGR21005	2021	67	MALE	DEATH	11/04/2021	COVISHIELD	SUDDEN CARDIAC DEATH WITH UNDERLYING CORONARY ARTERY DISEASE	C	05/04/2022
46	IND(CO-AEFI)KEPTM21009	2021	60	FEMALE	HOSPITALIZED AND RECOVERED	23-06-2021	COVISHIELD	CUTANEOUS VASCULITIS	B1	05/04/2022
47	IND(CO-AEFI)KEENK21008	2021	58	MALE	DEATH	22-06-2021	COVISHIELD	SUDDEN CARDIAC DEATH IN A CHRONIC SMOKER WITH DIABETES MELLITUS AND HYPERTENSION	C	05/04/2022
48	IND(CO-AEFI)KABMP21028	2021	28	MALE	HOSPITALIZED AND RECOVERED	03/07/2021	COVISHIELD	YOUNG STROKE	B1	05/04/2022
49	IND(CO-AEFI)RJPR21017	2021	52	FEMALE	SEVERE AND RECOVERED	09/04/2021	COVISHIELD	THROMBOSIS WITH THROMBOCYTOPENIA SYNDROME	A1	05/04/2022

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50	IND(CO-AEFI)RJPR21016	2021	58	MALE	HOSPITALIZED AND RECOVERED	19-04-2021	COVISHIELD	CEREBROVASCULAR ACCIDENT IN A KNOWN CASE OF HYPERTENSION, DIABETES MELLITUS AND CORONARY ARTERY DISEASE	C	05/04/2022
51	IND(CO-AEFI)KEENK21010	2021	46	MALE	DEATH	27-06-2021	COVISHIELD	SUDDEN CARDIAC DEATH WITH POST MORTEM EVIDENCE OF OCCLUSIVE CORONARY ARTERY DISEASE	C	05/04/2022
52	IND(CO-AEFI)MPSNI21006	2021	81	MALE	DEATH	22/07/2021	COVISHIELD	SUDDEN CARDIAC DEATH IN A SMOKER AND ALCOHOLIC WITH UNDERLYING CORONARY ARTERY DISEASE	C	05/04/2022
53	IND(CO-AEFI)GUKTC21001	2021	65	MALE	HOSPITALIZED AND RECOVERED	05/05/2021	COVISHIELD	DENGUE FEVER	C	05/04/2022
54	IND(CO-AEFI)WBDJL21027	2021	20	FEMALE	HOSPITALIZED AND RECOVERED	19/07/2021	COVISHIELD	ANXIETY REACTION	A4	05/04/2022
55	IND(CO-AEFI)DLSOU21017	2021	22	FEMALE	HOSPITALIZED AND RECOVERED	11/06/2021	COVISHIELD	THROMBOCYTOPENIA WITH MUCOSAL BLEEDING	A1	05/04/2022
56	IND(CO-AEFI)MPDDR21003	2021	48	MALE	DEATH	28/07/2021	COVISHIELD	PERICARDIAL EFFUSION WITH HEPATOSPLENOMEGALY	C	05/04/2022
57	IND(CO-AEFI)HAJUR21001	2021	23	FEMALE	HOSPITALIZED AND RECOVERED	25-01-2021	COVISHIELD	ANXIETY REACTION	A4	05/04/2022
58	IND(CO-AEFI)TNTVM21001	2021	40	FEMALE	HOSPITALIZED AND RECOVERED	29/06/2021	COVISHIELD	THROMBOCYTOPENIA	A1	05/04/2022
59	IND(CO-AEFI)GOGON21038	2021	69	MALE	HOSPITALIZED AND RECOVERED	11/04/2021	COVISHIELD	ACUTE MYOCARDIAL INFARCTION WITH HYPOGLYCEMIA	C	05/04/2022
60	IND(CO-AEFI)KEPTM21010	2021	19	MALE	HOSPITALIZED AND RECOVERED	22-07-2021	COVISHIELD	THROMBOSIS WITH THROMBOCYTOPENIA SYNDROME	A1	05/04/2022
61	IND(CO-AEFI)TNK21002	2021	51	FEMALE	DEATH	09/08/2021	COVISHIELD	CORONARY ARTERY DISEASE WITH POST MORTEM EVIDENCE OF ATHEROSCLEROTIC CHANGES IN CORONARY ARTERIES AND LEFT VENTRICULAR HYPERTROPHY	C	05/04/2022
62	IND(CO-AEFI)KEAPZ21029	2021	54	MALE	DEATH	08/06/2021	COVAXIN	UNEXPLAINED DEATH	D	05/04/2022
63	IND(CO-AEFI)KETHR21039	2021	38	FEMALE	DEATH	26-07-2021	COVISHIELD	DIABETIC KETOACIDOSIS WITH SEPSIS	C	05/04/2022
64	IND(CO-AEFI)KABMP21030	2021	21	FEMALE	HOSPITALIZED AND RECOVERED	09/08/2021	COVISHIELD	ACUTE FEBRILE REACTION	A1	05/04/2022
65	IND(CO-AEFI)KAKPP21004	2021	28	FEMALE	DEATH	06/08/2021	COVISHIELD	ANTEPARTUM HEMORRHAGE WITH BLEEDING DIATHESIS	B1	05/04/2022
66	IND(CO-AEFI)ORJSP21003	2021	49	MALE	HOSPITALIZED AND RECOVERED	09/08/2021	COVISHIELD	CEREBROVASCULAR ACCIDENT IN A KNOWN CASE OF HYPERTENSION AND DYSLIPIDEMIA	C	05/04/2022
67	IND(CO-AEFI)TNTNV21003	2021	46	FEMALE	DEATH	07/08/2021	COVISHIELD	UNEXPLAINED DEATH	D	05/04/2022
68	IND(CO-AEFI)TNCNI21021	2021	57	MALE	HOSPITALIZED AND RECOVERED	15/08/2021	COVISHIELD	ACUTE GASTROENTERITIS AND SHOCK IN A KNOWN CASE OF CORONARY ARTERY DISEASE, OLD CEREBROVASCULAR ACCIDENT AND TYPE II DIABETES MELLITUS	C	05/04/2022
69	IND(CO-AEFI)MHGNA21001	2021	51	MALE	DEATH	29/06/2021	COVAXIN	UNEXPLAINED DEATH	D	05/04/2022
70	IND(CO-AEFI)UPBRL21015	2021	45	MALE	SEVERE AND RECOVERED	21/04/2021	COVISHIELD	ACUTE FEBRILE REACTION	A1	05/04/2022
71	IND(CO-AEFI)WBBBM21003	2021	23	FEMALE	HOSPITALIZED AND RECOVERED	12/08/2021	COVISHIELD	ACUTE FEBRILE REACTION	A1	05/04/2022
72	IND(CO-AEFI)KEKOT21010	2021	31	FEMALE	HOSPITALIZED AND RECOVERED	29/06/2021	COVISHIELD	GUILLAIN BARRE SYNDROME	B1	05/04/2022
73	IND(CO-AEFI)KEENK21016	2021	40	MALE	DEATH	30/07/2021	COVISHIELD	THROMBOSIS WITH THROMBOCYTOPENIA SYNDROME WITH APLA ANTIBODY POSITIVITY	B2	05/04/2022
74	IND(CO-AEFI)UPMRD21012	2021	51	FEMALE	DEATH	25/08/2021	COVISHIELD	UNEXPLAINED DEATH	D	05/04/2022

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75	IND(CO-AEFI)TNKKM21002	2021	63	MALE	DEATH	26/08/2021	COVISHIELD	SUDDEN CARDIAC DEATH IN A KNOWN CASE OF DIABETES MELLITUS	C	05/04/2022
76	IND(CO-AEFI)KEAPZ21037	2021	20	MALE	DEATH	25/08/2021	COVISHIELD	VOLVULUS OF SMALL INTESTINE, GANGRENE AND PERITONITIS	C	05/04/2022
77	IND(CO-AEFI)KEENK21018	2021	32	FEMALE	SEVERE AND RECOVERED	18/08/2021	COVISHIELD	ANAPHYLAXIS	A1	05/04/2022
78	IND(CO-AEFI)KEKLM21021	2021	35	FEMALE	HOSPITALIZED AND RECOVERED	08/07/2021	COVISHIELD	GUILLAIN BARRE SYNDROME	B1	05/04/2022
79	IND(CO-AEFI)UPCKT21001	2021	42	MALE	DEATH	03/08/2021	COVISHIELD	UNEXPLAINED DEATH	D	05/04/2022
80	IND(CO-AEFI)KETHR21050	2021	86	FEMALE	DEATH	03/08/2021	COVISHIELD	HEAD INJURY (INTRACRANIAL BLEED)	C	05/04/2022
81	IND(CO-AEFI)KETHR21051	2021	75	MALE	DEATH	03/08/2021	COVISHIELD	UNEXPLAINED DEATH	D	05/04/2022
82	IND(CO-AEFI)MPMDL21007	2021	39	MALE	DEATH	19/08/2021	COVISHIELD	EMPYEMA LUNG	C	05/04/2022
83	IND(CO-AEFI)KEKLM21023	2021	54	MALE	HOSPITALIZED AND RECOVERED	13/08/2021	COVISHIELD	VIRAL MENINGOENCEPHALITIS	C	05/04/2022
84	IND(CO-AEFI)TNTLR21004	2021	71	MALE	DEATH	27/08/2021	COVISHIELD	SUDDEN CARDIAC DEATH WITH UNDERLYING UNCONTROLLED DIABETES MELLITUS	C	05/04/2022
85	IND(CO-AEFI)WBCAL21039	2021	28	FEMALE	HOSPITALIZED AND RECOVERED	25/08/2021	COVISHIELD	HEMOPTYSIS	C	05/04/2022
86	IND(CO-AEFI)BIJMI21002	2021	71	FEMALE	DEATH	31/08/2021	COVISHIELD	SUDDEN CARDIAC DEATH	C	05/04/2022
87	IND(CO-AEFI)RJPR21018	2021	48	FEMALE	HOSPITALIZED AND RECOVERED	31/07/2021	COVAXIN	DEEP VEIN THROMBOSIS (LEFT SUBCLAVIAN VEIN)	B1	05/04/2022
88	IND(CO-AEFI)KABMP21034	2021	35	FEMALE	HOSPITALIZED AND RECOVERED	01/09/2021	COVISHIELD	ACUTE RIGHT THALAMIC INFARCT WITH NO KNOWN RISK FACTORS	B1	05/04/2022
89	IND(CO-AEFI)UPGRP21004	2021	45	MALE	DEATH	27/08/2021	COVISHIELD	SUDDEN CARDIAC DEATH IN KNOWN SMOKER AND ALCOHOLIC	C	05/04/2022
90	IND(CO-AEFI)MHTHN21021	2021	67	MALE	DEATH	27/07/2021	COVISHIELD	ACUTE GASTROENTERITIS WITH HYPOVOLEMIC SHOCK	C	05/04/2022
91	IND(CO-AEFI)UPCKT21002	2021	50	MALE	DEATH	27/08/2021	COVISHIELD	SUDDEN CARDIAC DEATH	B1	05/04/2022
92	IND(CO-AEFI)WBDJL21037	2021	32	MALE	DEATH	03/09/2021	COVAXIN	ACUTE CORONARY SYNDROME	B1	05/04/2022
93	IND(CO-AEFI)KEWYD21023	2021	46	MALE	HOSPITALIZED AND RECOVERED	06/07/2021	COVAXIN	HEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS	B1	05/04/2022
94	IND(CO-AEFI)ORBGH21005	2021	46	MALE	DEATH	08/09/2021	COVISHIELD	COVID-19 DISEASE	C	05/04/2022
95	IND(CO-AEFI)KETHR21056	2021	32	MALE	HOSPITALIZED AND RECOVERED	07/09/2021	COVISHIELD	VASOVAGAL ATTACK	A4	05/04/2022
96	IND(CO-AEFI)MPSNI21012	2021	53	FEMALE	DEATH	12/04/2021	COVISHIELD	UNEXPLAINED DEATH	D	05/04/2022
97	IND(CO-AEFI)MHCP21001	2021	33	MALE	DEATH	11/09/2021	COVISHIELD	UNEXPLAINED DEATH	D	05/04/2022
98	IND(CO-AEFI)KABMP21037	2021	69	FEMALE	DEATH	31/07/2021	COVAXIN	ACUTE CORONARY SYNDROME IN A KNOWN CASE OF DIABETES MELLITUS, HYPERTENSION AND ISCHAEMIC HEART DISEASE	C	05/04/2022
99	IND(CO-AEFI)HPSML21002	2021	22	FEMALE	HOSPITALIZED AND RECOVERED	27/05/2021	COVISHIELD	THROMBOSIS WITH THROMBOCYTOPENIA SYNDROME	A1	05/04/2022
100	IND(CO-AEFI)KEPTM21016	2021	43	MALE	HOSPITALIZED AND RECOVERED	03/08/2021	COVISHIELD	LONGITUDINALLY EXTENSIVE TRANVERSE MYELITIS	B1	05/04/2022
101	IND(CO-AEFI)UAGRA21003	2021	73	FEMALE	DEATH	05/05/2021	COVISHIELD	CORONARY ARTERY DISEASE WITH UNDERLYING DIABETES MELLITUS, HYPERTENSION WITH CONGESTIVE CARDIAC FAILURE	C	05/04/2022

CAUSALITY CLASSIFICATION OF 161 AEFI CASES APPROVED BY THE NATIONAL AEFI COMMITTEE ON 05-04-2022 (NEW DELHI)

A1 - VACCINE PRODUCT RELATED REACTION

A2 - VACCINE QUALITY DEFECT RELATED REACTION

A3 - IMMUNIZATION ERROR RELATED REACTION

A4 - IMMUNIZATION ANXIETY RELATED REACTION

B1 - TEMPORAL RELATIONSHIP IS CONSISTENT BUT THERE IS INSUFFICIENT DEFINITIVE EVIDENCE FOR VACCINE CAUSING EVENT

B2 - REVIEWING FACTORS RESULT IN CONFLICTING TRENDS OF CONSISTENCY AND INCONSISTENCY WITH CAUSAL ASSOCIATION TO IMMUNIZATION

C - COINCIDENTAL - UNDERLYING OR EMERGING CONDITION(S), OR CONDITIONS CAUSED BY EXPOSURE TO SOMETHING OTHER THAN VACCINE

D - UNCLASSIFIABLE

S. NO.	NATIONAL ID	YEAR	AGE (IN YEARS)	SEX	REASON FOR REPORTING/ OUTCOME	DATE OF VACCINATION (DD/MM/YYYY)	VACCINE	DIAGNOSIS	CLASSIFICATION* BY NATIONAL AEFI COMMITTEE	DATE OF APPROVAL BY NATIONAL AEFI COMMITTEE
102	IND(CO-AEFI)MHKLP21012	2021	33	FEMALE	DEATH	15/09/2021	COVISHIELD	INTRACEREBRAL HEMORRHAGE (SUBARACHNOID HEMORRHAGE, SUBDURAL HEMATOMA AND INTRA VENTRICULAR HEMORRHAGE)	C	05/04/2022
103	IND(CO-AEFI)UPBBK21005	2021	31	FEMALE	DEATH	31/08/2021	COVISHIELD	BILATERAL PNEUMONIA	C	05/04/2022
104	IND(CO-AEFI)UPPIL21007	2021	72	MALE	DEATH	02/09/2021	COVISHIELD	SUDDEN CARDIAC DEATH	C	05/04/2022
105	IND(CO-AEFI)UPMAI21003	2021	71	FEMALE	DEATH	20/09/2021	COVISHIELD	MYOCARDIAL INFARCTION WITH CARDIOGENIC SHOCK	C	05/04/2022
106	IND(CO-AEFI)UAGRA21004	2021	56	FEMALE	DEATH	08/09/2021	COVISHIELD	ACUTE RESPIRATORY DISTRESS SYNDROME	C	05/04/2022
107	IND(CO-AEFI)ORNRP21004	2021	50	FEMALE	DEATH	21/09/2021	COVISHIELD	SUDDEN CARDIAC DEATH WITH ACUTE PULMONARY EDEMA IN KNOWN CASE OF ALCOHOL USE DISORDER AND SMOKING	C	05/04/2022
108	IND(CO-AEFI)MHBMC21086	2021	74	MALE	DEATH	28/08/2021	COVISHIELD	CEREBROVASCULAR ACCIDENT (INTRACRANIAL BLEED) IN A KNOWN CASE OF HYPERTENSION AND DIABETES MELLITUS	C	05/04/2022
109	IND(CO-AEFI)UPAZG21003	2021	62	MALE	DEATH	14/09/2021	COVISHIELD	SUDDEN CARDIAC DEATH IN A KNOWN SMOKER AND ALCOHOLIC WITH UNDERLYING DIABETES MELLITUS AND HYPERTENSION	C	05/04/2022
110	IND(CO-AEFI)HAPNP21010	2021	41	MALE	DEATH	25/09/2021	COVISHIELD	SUDDEN CARDIAC DEATH WITH POST MORTEM EVIDENCE OF CORONARY ARTERY OCCLUSION	C	05/04/2022
111	IND(CO-AEFI)CGRNG21007	2021	27	FEMALE	HOSPITALIZED AND RECOVERED	22/09/2021	COVISHIELD	ALLERGIC REACTION	A1	05/04/2022
112	IND(CO-AEFI)KADKN21002	2021	28	FEMALE	HOSPITALIZED AND RECOVERED	19/06/2021	COVISHIELD	ACUTE FEBRILE ILLNESS WITH PELVIC INFLAMMATORY DISEASE	C	05/04/2022
113	IND(CO-AEFI)KEAPZ21039	2021	73	MALE	DEATH	07/08/2021	COVISHIELD	SUDDEN CARDIAC DEATH IN AN OLD CASE OF INFERIOR WALL MYOCARDIAL INFARCTION, ANKYLOSING SPONDYLITIS AND CEREBROVASCULAR ACCIDENT	C	05/04/2022
114	IND(CO-AEFI)TSHYD21024	2021	61	FEMALE	DEATH	10/04/2021	COVISHIELD	SUDDEN CARDIAC DEATH IN A KNOWN CASE OF DIABETES MELLITUS, HYPERTENSION AND ISCHAEMIC STROKE	C	05/04/2022
115	IND(CO-AEFI)KETHR21061	2021	22	FEMALE	HOSPITALIZED AND RECOVERED	18/07/2021	COVISHIELD	THROMBOSIS WITH THROMBOCYTOPENIA SYNDROME	A1	05/04/2022
116	IND(CO-AEFI)MPIDR21010	2021	24	FEMALE	HOSPITALIZED AND RECOVERED	24/09/2021	COVAXIN	SUDDEN INTRAUTERINE DEATH WITH POLYHYDRAMNIOS	C	05/04/2022
117	IND(CO-AEFI)WBND21001	2021	61	FEMALE	DEATH	21/09/2021	COVISHIELD	UNEXPLAINED DEATH	D	05/04/2022
118	IND(CO-AEFI)WBDDJ21002	2021	51	FEMALE	DEATH	29/09/2021	COVISHIELD	UNEXPLAINED DEATH	D	05/04/2022
119	IND(CO-AEFI)RJPR21021	2021	40	MALE	HOSPITALIZED AND RECOVERED	13/09/2021	COVISHIELD	GENERALIZED TONIC-CLONIC SEIZURE WITH HYPERTENSION	B2	05/04/2022
120	IND(CO-AEFI)KETHR21065	2021	74	MALE	DEATH	23/09/2021	COVISHIELD	SUDDEN CARDIAC DEATH IN KNOWN CASE OF CORONARY ARTERY DISEASE, DIABETES MELLITUS AND HYPERTENSION	C	05/04/2022
121	IND(CO-AEFI)KETHR21066	2021	85	MALE	DEATH	21/09/2021	COVISHIELD	SUDDEN CARDIAC DEATH IN A PERSON WITH DEMENTIA, HYPERTENSION, URINARY TRACT INFECTION AND UROSEPSIS	C	05/04/2022
122	IND(CO-AEFI)KETHR21068	2021	66	FEMALE	DEATH	11/09/2021	COVAXIN	SUDDEN CARDIAC DEATH IN A KNOWN CASE OF VALVULAR HEART DISEASE AND SEIZURE DISORDER	C	05/04/2022
123	IND(CO-AEFI)MNCCP21001	2021	27	MALE	DEATH	03/07/2021	COVISHIELD	UNEXPLAINED DEATH	D	05/04/2022
124	IND(CO-AEFI)MPGUN21005	2021	27	FEMALE	HOSPITALIZED AND RECOVERED	19/09/2021	COVISHIELD	SPONTANEOUS ABORTION	C	05/04/2022

CAUSALITY CLASSIFICATION OF 161 AEFI CASES APPROVED BY THE NATIONAL AEFI COMMITTEE ON 05-04-2022 (NEW DELHI)

A1 - VACCINE PRODUCT RELATED REACTION

A2 - VACCINE QUALITY DEFECT RELATED REACTION

A3 - IMMUNIZATION ERROR RELATED REACTION

A4 - IMMUNIZATION ANXIETY RELATED REACTION

B1 - TEMPORAL RELATIONSHIP IS CONSISTENT BUT THERE IS INSUFFICIENT DEFINITIVE EVIDENCE FOR VACCINE CAUSING EVENT

B2 - REVIEWING FACTORS RESULT IN CONFLICTING TRENDS OF CONSISTENCY AND INCONSISTENCY WITH CAUSAL ASSOCIATION TO IMMUNIZATION

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S. NO.	NATIONAL ID	YEAR	AGE (IN YEARS)	SEX	REASON FOR REPORTING/ OUTCOME	DATE OF VACCINATION (DD/MM/YYYY)	VACCINE	DIAGNOSIS	CLASSIFICATION* BY NATIONAL AEFI COMMITTEE	DATE OF APPROVAL BY NATIONAL AEFI COMMITTEE
125	IND(CO-AEFI)KEENK21023	2021	61	FEMALE	HOSPITALIZED AND RECOVERED	23/06/2021	COVISHIELD	GUILLAIN BARRE SYNDROME	B1	05/04/2022
126	IND(CO-AEFI)GOGOS21028	2021	67	FEMALE	HOSPITALIZED AND RECOVERED	25/08/2021	COVISHIELD	FEVER AND GENERALIZED WEAKNESS	A1	05/04/2022
127	IND(CO-AEFI)KEPTM21017	2021	40	MALE	DEATH	25/09/2021	COVISHIELD	SUDDEN CARDIAC DEATH IN A KNOWN CASE OF CHRONIC GLOMERULONEPHRITIS WITH CHRONIC KIDNEY DISEASE	C	05/04/2022
128	IND(CO-AEFI)DLNOR21005	2021	30	FEMALE	DEATH	22/09/2021	COVAXIN	BILATERAL PNEUMONIA WITH SEPTICAEMIA AND ACUTE KIDNEY INJURY	C	05/04/2022
129	IND(CO-AEFI)KEENK21027	2021	44	MALE	HOSPITALIZED AND RECOVERED	27/07/2021	COVISHIELD	BELL'S PALSRY WITH DIABETES MELLITUS	B2	05/04/2022
130	IND(CO-AEFI)KEENK21032	2021	24	MALE	HOSPITALIZED AND RECOVERED	13/07/2021	COVISHIELD	THROMBOSIS WITH THROMBOCYTOPENIA SYNDROME	A1	05/04/2022
131	IND(CO-AEFI)KEENK21026	2021	34	FEMALE	HOSPITALIZED AND RECOVERED	26/07/2021	COVISHIELD	THROMBOSIS WITH THROMBOCYTOPENIA SYNDROME	A1	05/04/2022
132	IND(CO-AEFI)DLWES21014	2021	50	FEMALE	HOSPITALIZED AND RECOVERED	09/10/2021	COVISHIELD	ANAPHYLAXIS	A1	05/04/2022
133	IND(CO-AEFI)UPGZP21001	2021	62	FEMALE	DEATH	23/09/2021	COVISHIELD	SUDDEN CARDIAC DEATH WITH UNDERLYING CORONARY ARTERY DISEASE	C	05/04/2022
134	IND(CO-AEFI)KETHR21073	2021	34	FEMALE	DEATH	16/10/2021	COVISHIELD	POST PARTUM HEMORRHAGE WITH AMNIOTIC FLUID EMBOLISM	C	05/04/2022
135	IND(CO-AEFI)GUGNR21007	2021	32	MALE	HOSPITALIZED AND RECOVERED	09/03/2021	COVAXIN	SUBACUTE SCLEROSING PANENCEPHALITIS	C	05/04/2022
136	IND(CO-AEFI)MPUMR21002	2021	65	MALE	DEATH	10/07/2021	COVISHIELD	SUDDEN CARDIAC DEATH IN KNOWN CASE OF CORONARY ARTERY DISEASE, CHRONIC OBSTRUCTIVE PULMONARY DISEASE AND COR PULMONALE	C	05/04/2022
137	IND(CO-AEFI)TNTLR21003	2021	23	FEMALE	HOSPITALIZED AND RECOVERED	05/07/2021	COVISHIELD	ACUTE FEBRILE REACTION	A1	05/04/2022
138	IND(CO-AEFI)SISTH21007	2021	87	FEMALE	DEATH	24/04/2021	COVISHIELD	SUDDEN CARDIAC DEATH IN KNOWN CASE OF CORONARY ARTERY DISEASE, HYPERTENSION AND HEART FAILURE	C	05/04/2022
139	IND(CO-AEFI)CGBTR21004	2021	53	FEMALE	DEATH	25/10/2021	COVISHIELD	UNEXPLAINED DEATH	D	05/04/2022
140	IND(CO-AEFI)MHBMC21101	2021	53	FEMALE	DEATH	08/09/2021	COVAXIN	DIABETES MELLITUS WITH POSTERIOR CIRCULATION THROMBOTIC STROKE	C	05/04/2022
141	IND(CO-AEFI)UPMRD21013	2021	31	FEMALE	DEATH	27/10/2021	COVISHIELD	UNEXPLAINED DEATH	D	05/04/2022
142	IND(CO-AEFI)KABEL21018	2021	43	MALE	SEVERE AND RECOVERED	17/07/2021	COVISHIELD	RECURRENT LEFT BRACHIAL NEURITIS WITH DIABETES MELLITUS	C	05/04/2022
143	IND(CO-AEFI)KABEL21016	2021	53	MALE	DEATH	17/09/2021	COVISHIELD	SUDDEN CARDIAC DEATH IN A KNOWN CASE OF HYPERTENSION AND CEREBROVASCULAR ACCIDENT	C	05/04/2022
144	IND(CO-AEFI)KABEL21017	2021	20	FEMALE	HOSPITALIZED AND RECOVERED	17/09/2021	COVISHIELD	CEREBRAL VENOUS SINUS THROMBOSIS WITH HEMORRHAGIC INFARCT	B1	05/04/2022
145	IND(CO-AEFI)WBJPG21014	2021	60	FEMALE	HOSPITALIZED AND RECOVERED	15/09/2021	COVISHIELD	ANXIETY REACTION	A4	05/04/2022
146	IND(CO-AEFI)MHRTG21003	2021	58	MALE	DEATH	04/09/2021	COVISHIELD	ACUTE MYOCARDIAL INFARCTION IN A KNOWN CASE OF DIABETES MELLITUS AND HYPERTENSION	C	05/04/2022
147	IND(CO-AEFI)MHOB21001	2021	35	FEMALE	HOSPITALIZED AND RECOVERED	28/05/2021	COVISHIELD	GUILLAIN BARRE SYNDROME	B1	05/04/2022

CAUSALITY CLASSIFICATION OF 161 AEFI CASES APPROVED BY THE NATIONAL AEFI COMMITTEE ON 05-04-2022 (NEW DELHI)

A1 - VACCINE PRODUCT RELATED REACTION

A2 - VACCINE QUALITY DEFECT RELATED REACTION

A3 - IMMUNIZATION ERROR RELATED REACTION

A4 - IMMUNIZATION ANXIETY RELATED REACTION

B1 - TEMPORAL RELATIONSHIP IS CONSISTENT BUT THERE IS INSUFFICIENT DEFINITIVE EVIDENCE FOR VACCINE CAUSING EVENT

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148	IND(CO-AEFI)WBBDN21027	2021	49	MALE	DEATH	19/11/2021	COVISHIELD	INTRACEREBRAL HAEMORRHAGE WITH HYPERTENSION	C	05/04/2022

CAUSALITY CLASSIFICATION OF 161 AEFI CASES APPROVED BY THE NATIONAL AEFI COMMITTEE ON 05-04-2022 (NEW DELHI)

A1 - VACCINE PRODUCT RELATED REACTION

A2 - VACCINE QUALITY DEFECT RELATED REACTION

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149	IND(CO-AEFI)MHSLR21002	2021	34	FEMALE	HOSPITALIZED AND RECOVERED	16/10/2021	COVISHIELD	THROMBOSIS WITH THROMBOCYTOPENIA SYNDROME	A1	05/04/2022
150	IND(CO-AEFI)BIMZF21004	2021	54	MALE	DEATH	02/04/2021	COVISHIELD	UNEXPLAINED DEATH	D	05/04/2022
151	IND(CO-AEFI)ASDRG21001	2021	75	FEMALE	DEATH	28/11/2021	COVISHIELD	UNEXPLAINED DEATH	D	05/04/2022
152	IND(CO-AEFI)MHTHN21026	2021	32	MALE	HOSPITALIZED AND RECOVERED	18/09/2021	COVISHIELD	SOLITARY GENERALIZED TONIC-CLONIC SEIZURE	B1	05/04/2022
153	IND(CO-AEFI)WBBKR21005	2021	52	MALE	HOSPITALIZED AND RECOVERED	20/09/2021	COVISHIELD	INTRACRANIAL BLEED WITH HYPERTENSIVE EMERGENCY	C	05/04/2022
154	IND(CO-AEFI)ORNRP21006	2021	27	FEMALE	DEATH	24/11/2021	COVISHIELD	UNEXPLAINED DEATH	D	05/04/2022
155	IND(CO-AEFI)MPPAN21002	2021	21	FEMALE	SEVERE AND RECOVERED	01/12/2021	COVAXIN	PRE TERM BIRTH	C	05/04/2022
156	IND(CO-AEFI)KEKLM21026	2021	37	FEMALE	HOSPITALIZED AND RECOVERED	10/09/2021	COVISHIELD	SEVERE PREGNANCY INDUCED HYPERTENSION WITH ABRUPTIO WITH IINTRAUTERINE DEATH	C	05/04/2022
157	IND(CO-AEFI)CGMMD21010	2021	21	FEMALE	HOSPITALIZED AND RECOVERED	04/10/2021	COVISHIELD	PRIMI WITH 26 WEEKS PREGNANCY WITH UNEXPLAINED INTRAUTERINE DEATH	C	05/04/2022
158	IND(CO-AEFI)HAJND21005	2021	24	MALE	DEATH	27/12/2021	COVISHIELD	UNEXPLAINED DEATH	D	05/04/2022
159	IND(CO-AEFI)WBCAL21048	2021	70	MALE	DEATH	30/04/2021	COVAXIN	GUILLAIN BARRE SYNDROME	B1	05/04/2022
160	IND(CO-AEFI)HAPKL21008	2021	22	MALE	HOSPITALIZED AND RECOVERED	06/08/2021	COVISHIELD	APLASTIC ANEMIA	C	05/04/2022
161	IND(CO-AEFI)KAUDU21009	2021	51	MALE	HOSPITALIZED AND RECOVERED	28/05/2021	COVISHIELD	GUILLAIN BARRE SYNDROME	B2	05/04/2022