

# Vaccine Safety Core Data Elements

Version 1, August 2021

## *Instructions for the investigator and questionnaire designer:*

This document describes the CITF core data elements (CDE) that should be collected by CITF-funded vaccine safety projects. CITF based the questions and responses on national surveys, CDE for other CITF-funded projects, and the Adverse Event Following Immunization (AEFI) for COVID-19 immunization (<https://www.canada.ca/en/public-health/services/immunization/reporting-adverse-events-following-immunization/user-guide-completion-submission-ae-fi-reports.html>). These questions are based on the national form for Report Adverse Events Following Immunization (AEFI) v. Jan, 2020 with COVID-19 detail added March 18, 2021.

We recommend that the questionnaire be administered by trained research staff due to the knowledge of medical terminology needed to ascertain possible adverse events following COVID-19 immunization (pp. 10-19). The main AEFI questions use branching logic to skip the detailed response sections when no event was experienced. The detailed sections will likely only apply to a small number of study participants. Therefore, we recommend using questionnaire design and administration software such as REDCap or Lime Survey, not paper forms. If you need assistance with these software packages, please contact the CITF data manager.

If you are collecting vaccine safety data using self-administered questionnaires, please share the questionnaire with the CITF Data Management unit so that they can anticipate the change in format.

The responses to these CDE are the data you will be asked to be share with the CITF, where legally and ethically possible, once you have signed a data sharing agreement with the CITF and your data collection is complete. If you add sub-questions or additional precision to the CDE questions, you do not need to share the additional detail.

The **CDE questions in red text** or **instructions in italicized red text** should be answered by the investigator or interviewer, not directly posed to the study participant.

You should complete this module for each COVID-19 vaccine dose the participant received. That is, if you are only collecting vaccine safety data, the following ‘Vaccination basics’ questions should be added to the beginning the ‘Vaccine safety’ questions (Q40-43). If COVID-19 test and vaccination history module is used, skip to ‘Vaccine safety’ Q50.

Please note that completing this questionnaire does not replace official AEFI reporting. **If a participant responds YES to ANY of questions 51-55, please direct the participant to their health care provider or a health care professional on your study team to determine whether the signs or symptoms should be reported as an AEFI.** If it is reportable and not already done for this episode, complete and submit the national AEFI (<https://www.canada.ca/en/public-health/services/immunization/reporting-adverse-events-following-immunization.html> or your provincial equivalent).

## Vaccination basics

Q #	CITF Adult General Vaccine CDE
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00	Participant unique identifier (same across modules and visits)
01.a	Date of interview  DAY / MO / YR
40.	Have you been vaccinated against COVID-19? (Answer 'Yes' if you have received at least one dose of a COVID-19 vaccine)  NO .....00 YES .....01 DON'T KNOW .....98
41.	How many doses have you received?  ONE .....01 TWO .....02 MORE THAN TWO .....03 DON'T KNOW .....98

Repeat the following section for each dose (make this a repeatable instrument within visit e.g., baseline, if needed)

Q #	CITF Adult General Vaccine CDE repeatable form
40.a.	<i>This question is a screen and placeholder for an e-questionnaire repeatable form [e.g., a REDCap repeated instrument]. It is optional if not needed for your questionnaire design.</i>  You answered [Q40 response, if = '00, 98'] to "Have you been vaccinated against COVID-19?"  Do you have a COVID-19 vaccine scheduled?  NO .....00 YES .....01 DON'T KNOW .....98 PREFER NOT TO ANSWER .....99
41.a.	You answered that you have had [Q41 response, if Q40 = '01'] doses. For which dose are you completing this form?  FIRST .....01 SECOND .....02 LATEST OF 3 OR MORE .....03 DON'T KNOW .....98

Q #	CITF Adult General Vaccine CDE repeatable form
42.	<p>When did you receive this dose of the COVID-19 vaccine?</p> <p>___ / ___ / ___  DAY            MO            YR</p> <p>DON'T KNOW .....98</p>
43.	<p>Which vaccine did you receive?</p> <p>PFIZER AND BIONTECH mRNA .....01  MODERNA mRNA .....02  ASTRAZENECA OXFORD .....03  JOHNSON &amp; JOHNSON (JANSSEN) .....04  OTHER .....09  (SPECIFY THE VACCINE) _____  DON'T KNOW .....98</p>

Vaccine safety

Q #	CITF Adult Vaccine Safety CDE (repeatable form) v.1
50.	<p><i>If applicable (e.g. sex = female, age 14-55 years)</i></p> <p>a. Were you pregnant at the time of this COVID-19 vaccination?</p> <p>NO .....00 → 51.c  YES .....01 → 51.b  DON'T KNOW .....98 → 51.c  PREFER NOT TO ANSWER .....99 → 51.c</p> <p>b. If YES, how many weeks gestation (or trimester)?</p> <p>0-14 WEEKS (1ST TRIMESTER) ...01  15-28 WEEKS (2ND TRIMESTER)...02  29-42 WEEKS (3RD TRIMESTER)...03  DON'T KNOW .....98  PREFER NOT TO ANSWER .....99</p> <p>c. Were you breastfeeding at the time of this COVID-19 vaccination?</p> <p>NO .....00  YES .....01  DON'T KNOW .....98  PREFER NOT TO ANSWER .....99</p>

Q #	CITF Adult Vaccine Safety CDE (repeatable form) v.1			
<b>Signs and symptoms after [this] COVID-19 vaccine:</b>				
51.a.	Local reaction at or near vaccination site? (e.g. swelling, pain, drainage)			
	NO .....00 → 52			
	YES .....01 → 51.b			
	DON'T KNOW .....98 → 52			
51.b.	Days from immunization to onset of 1 <sup>st</sup> local reaction (same day = 0)			
	__ __ DAYS			
	DON'T KNOW			
51.c	Select the type of local reaction			
		YES	NO	DON'T KNOW
	1. Infected abscess	01	00	98
	2. Sterile abscess	01	00	98
	3. Cellulitis	01	00	98
	4. Nodule	01	00	98
	5. Lymphadenitis	01	00	98
	6. Reaction stretches joint-to-joint	01	00	98
	7. Reaction crosses joint(s)	01	00	98
	8. Other (specify)			
51.d	For any local reaction indicated above, check all signs and symptoms that apply			
		YES	NO	DON'T KNOW
	1. Swelling	01	00	98
	2. Pain	01	00	98
	3. Tenderness	01	00	98
	4. Erythema	01	00	98
	5. Warmth	01	00	98
	6. Induration	01	00	98
	7. Rash	01	00	98
	8. Palpable fluctuance	01	00	98
	9. Fluid collection shown by imaging technique (e.g. MRI, CT, ultrasound)	01	00	98
	10. Spontaneous/surgical drainage	01	00	98
	11. Microbial results	01	00	98
	12. Lymphangitic streaking			
	13. Regional lymphadenopathy			

Q #	CITF Adult Vaccine Safety CDE (repeatable form) v.1																												
52.a.	Allergic or allergic-like events (e.g., hives, angioedema)?  NO .....00 → 53 YES .....01 → 52.b DON'T KNOW .....98 → 53																												
52.b.	Days from immunization to onset of 1 <sup>st</sup> allergic or allergic-like symptom or sign (same day = 0)  ___ ___ DAYS  DON'T KNOW																												
52.c	Select the type of allergic or allergic-like reaction:  ANAPHYLAXIS .....01 OCULO-RESPIRATORY SYNDROME (ORS) .....02 OTHER ALLERGIC EVENTS .....03																												
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52.d	Skin / mucosal  <table border="1" data-bbox="337 930 1385 1241"> <thead> <tr> <th data-bbox="337 930 943 961">i.</th> <th data-bbox="943 930 1060 961">YES</th> <th data-bbox="1060 930 1170 961">NO</th> <th data-bbox="1170 930 1385 961">DON'T KNOW</th> </tr> </thead> <tbody> <tr> <td data-bbox="337 961 943 993">1. Urticaria (hives)</td> <td data-bbox="943 961 1060 993">01</td> <td data-bbox="1060 961 1170 993">00</td> <td data-bbox="1170 961 1385 993">98</td> </tr> <tr> <td data-bbox="337 993 943 1024">2. Erythema</td> <td data-bbox="943 993 1060 1024">01</td> <td data-bbox="1060 993 1170 1024">00</td> <td data-bbox="1170 993 1385 1024">98</td> </tr> <tr> <td data-bbox="337 1024 943 1056">3. Pruritus</td> <td data-bbox="943 1024 1060 1056">01</td> <td data-bbox="1060 1024 1170 1056">00</td> <td data-bbox="1170 1024 1385 1056">98</td> </tr> <tr> <td data-bbox="337 1056 943 1098">4. Paraesthesia (prickling or tingling)</td> <td data-bbox="943 1056 1060 1098">01</td> <td data-bbox="1060 1056 1170 1098">00</td> <td data-bbox="1170 1056 1385 1098">98</td> </tr> <tr> <td data-bbox="337 1098 943 1129">5. Flushing</td> <td data-bbox="943 1098 1060 1129">01</td> <td data-bbox="1060 1098 1170 1129">00</td> <td data-bbox="1170 1098 1385 1129">98</td> </tr> <tr> <td data-bbox="337 1129 943 1161">6. Other Rash</td> <td data-bbox="943 1129 1060 1161">01</td> <td data-bbox="1060 1129 1170 1161">00</td> <td data-bbox="1170 1129 1385 1161">98</td> </tr> </tbody> </table> ii. Was the skin or mucosal reaction generalized or localized?  GENERALIZED .....01 → [53.d.iv] LOCALIZED .....02 → next (53.d.iii) DON'T KNOW .....98 → [53.d.iv] iii. If localized, specify the site  _____ iv. Angioedema?  NO .....00 → 53 YES .....01 → 52.b DON'T KNOW .....98 → 53	i.	YES	NO	DON'T KNOW	1. Urticaria (hives)	01	00	98	2. Erythema	01	00	98	3. Pruritus	01	00	98	4. Paraesthesia (prickling or tingling)	01	00	98	5. Flushing	01	00	98	6. Other Rash	01	00	98
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	<p>v. Angioedema (swelling) visible?</p> <p>YES .....00  NO, PARTICIPANT REPORTED SENSATION OF SWELLING ....01</p> <table border="1" data-bbox="337 394 1385 873"> <thead> <tr> <th colspan="4">vi. Angioedema sites:</th> </tr> <tr> <th></th> <th>YES</th> <th>NO</th> <th>DON'T KNOW</th> </tr> </thead> <tbody> <tr><td>1. Tongue</td><td>01</td><td>00</td><td>98</td></tr> <tr><td>2. Throat</td><td>01</td><td>00</td><td>98</td></tr> <tr><td>3. Uvula</td><td>01</td><td>00</td><td>98</td></tr> <tr><td>4. Larynx</td><td>01</td><td>00</td><td>98</td></tr> <tr><td>5. Lip</td><td>01</td><td>00</td><td>98</td></tr> <tr><td>6. Eyelids</td><td>01</td><td>00</td><td>98</td></tr> <tr><td>7. Eyes, red bilateral</td><td>01</td><td>00</td><td>98</td></tr> <tr><td>8. Eye, red unilateral</td><td>01</td><td>00</td><td>98</td></tr> <tr><td>9. Eye(s), itchy</td><td>01</td><td>00</td><td>98</td></tr> <tr><td>10. Face</td><td>01</td><td>00</td><td>98</td></tr> <tr><td>11. Limbs</td><td>01</td><td>00</td><td>98</td></tr> <tr><td>12. Other, specify</td><td></td><td></td><td></td></tr> </tbody> </table>	vi. Angioedema sites:					YES	NO	DON'T KNOW	1. Tongue	01	00	98	2. Throat	01	00	98	3. Uvula	01	00	98	4. Larynx	01	00	98	5. Lip	01	00	98	6. Eyelids	01	00	98	7. Eyes, red bilateral	01	00	98	8. Eye, red unilateral	01	00	98	9. Eye(s), itchy	01	00	98	10. Face	01	00	98	11. Limbs	01	00	98	12. Other, specify			
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	14. Difficulty swallowing	01	00	98
	15. Difficulty breathing	01	00	98
	16. Chest tightness	01	00	98
52.g.	Gastrointestinal:			
		YES	NO	DON'T KNOW
	1. Diarrhea	01	00	98
	2. Abdominal pain	01	00	98
	3. Nausea	01	00	98
	4. Vomiting	01	00	98
53.a.	Neurologic events (e.g., meningitis, paralysis, seizure)			
	NO .....00 → 54			
	YES .....01 → 53.b			
	DON'T KNOW .....98 → 54			
53.b.	Days from immunization to onset of 1st neurologic symptom or sign (same day = 0)			
	__ __ DAYS			
	DON'T KNOW			
53.c.	Select the type of physician-diagnosed neurologic reactions			
		YES	NO	DON'T KNOW
	1. Meningitis	01	00	98
	2. Encephalopathy/Encephalitis	01	00	98
	3. Guillain-Barre Syndrome	01	00	98
	4. Bell's Palsy	01	00	98
	5. Other Paralysis	01	00	98
	6. Myelitis/transverse myelitis	01	00	98
	7. Subacute sclerosing panencephalitis	01	00	98
	8. Other neurologic diagnosis (specify)			
53.d.	i. Seizure:			
	NO .....00 → 53.e			
	YES, PARTIAL .....01 → next (53.d.iii)			
	YES, GENERALIZED .....02 → next (53.d.ii)			
	DON'T KNOW .....98 → 53.e			
	ii. Type of Generalized Seizure:			
	TONIC .....01			
	CLONIC .....02			
	TONIC-CLONIC .....03			
	ATONIC .....04			
	ABSENCE .....05			
	MYOCLONIC .....06			
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	<table border="1" data-bbox="337 258 1385 468"> <tr> <td colspan="4" data-bbox="337 258 1385 294">iii. Seizure details:</td> </tr> <tr> <td data-bbox="337 294 943 329"></td> <td data-bbox="943 294 1062 329">YES</td> <td data-bbox="1062 294 1170 329">NO</td> <td data-bbox="1170 294 1385 329">DON'T KNOW</td> </tr> <tr> <td data-bbox="337 329 943 365">1. Sudden loss of consciousness</td> <td data-bbox="943 329 1062 365">01</td> <td data-bbox="1062 329 1170 365">00</td> <td data-bbox="1170 329 1385 365">98</td> </tr> <tr> <td data-bbox="337 365 943 428">2. Witnessed by healthcare professional</td> <td data-bbox="943 365 1062 428">01</td> <td data-bbox="1062 365 1170 428">00</td> <td data-bbox="1170 365 1385 428">98</td> </tr> <tr> <td data-bbox="337 428 943 468">3. Previous history of seizures</td> <td data-bbox="943 428 1062 468">01</td> <td data-bbox="1062 428 1170 468">00</td> <td data-bbox="1170 428 1385 468">98</td> </tr> </table> <p data-bbox="337 516 1105 548">iv. If 'Previous history of seizures', type:</p> <p data-bbox="337 583 704 615">FEBRILE .....01</p> <p data-bbox="337 615 704 646">AFEBRILE .....02</p> <p data-bbox="337 646 704 678">UNKNOWN .....98</p>	iii. Seizure details:					YES	NO	DON'T KNOW	1. Sudden loss of consciousness	01	00	98	2. Witnessed by healthcare professional	01	00	98	3. Previous history of seizures	01	00	98																												
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3. Personality change lasting ≥ 24 hrs	01	00	98																																														
4. Focal or multifocal neurologic sign(s)	01	00	98																																														
5. Fever (≥38.0°C)	01	00	98																																														
6. Anaesthesia (numbness)	01	00	98																																														
7. Burning	01	00	98																																														
8. Formication	01	00	98																																														
9. Paraesthesia	01	00	98																																														
10. Other neurologic sign or symptom (specify)																																																	
53.f	<table border="1" data-bbox="337 1276 1385 1539"> <tr> <td colspan="4" data-bbox="337 1276 1385 1312">Abnormal test results</td> </tr> <tr> <td data-bbox="337 1312 943 1348"></td> <td data-bbox="943 1312 1062 1348">YES</td> <td data-bbox="1062 1312 1170 1348">NO</td> <td data-bbox="1170 1312 1385 1348">DON'T KNOW</td> </tr> <tr> <td data-bbox="337 1348 943 1383">1. CSF abnormality</td> <td data-bbox="943 1348 1062 1383">01</td> <td data-bbox="1062 1348 1170 1383">00</td> <td data-bbox="1170 1348 1385 1383">98</td> </tr> <tr> <td data-bbox="337 1383 943 1419">2. EEG abnormality</td> <td data-bbox="943 1383 1062 1419">01</td> <td data-bbox="1062 1383 1170 1419">00</td> <td data-bbox="1170 1383 1385 1419">98</td> </tr> <tr> <td data-bbox="337 1419 943 1455">3. EMG abnormality</td> <td data-bbox="943 1419 1062 1455">01</td> <td data-bbox="1062 1419 1170 1455">00</td> <td data-bbox="1170 1419 1385 1455">98</td> </tr> <tr> <td data-bbox="337 1455 943 1491">4. Neuroimaging abnormality</td> <td data-bbox="943 1455 1062 1491">01</td> <td data-bbox="1062 1455 1170 1491">00</td> <td data-bbox="1170 1455 1385 1491">98</td> </tr> <tr> <td data-bbox="337 1491 943 1539">5. Brain/spinal cord histopathologic abnormality</td> <td data-bbox="943 1491 1062 1539">01</td> <td data-bbox="1062 1491 1170 1539">00</td> <td data-bbox="1170 1491 1385 1539">98</td> </tr> </table>	Abnormal test results					YES	NO	DON'T KNOW	1. CSF abnormality	01	00	98	2. EEG abnormality	01	00	98	3. EMG abnormality	01	00	98	4. Neuroimaging abnormality	01	00	98	5. Brain/spinal cord histopathologic abnormality	01	00	98																				
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54.a.	<p data-bbox="337 1549 1227 1608">Other serious or unexpected health event? (e.g., arthritis, thrombocytopenia, blood clotting)</p> <p data-bbox="337 1644 1344 1675">NO .....00 → [internal branching check]</p> <p data-bbox="337 1675 964 1707">YES .....01 → 54.b</p> <p data-bbox="337 1707 1344 1738">DON'T KNOW .....98 → [internal branching check]</p>																																																



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54.c.	<table border="1" data-bbox="337 422 1382 667"> <thead> <tr> <th data-bbox="337 422 943 464">Other diagnoses (physician diagnosed)</th> <th data-bbox="943 422 1062 464">YES</th> <th data-bbox="1062 422 1170 464">NO</th> <th data-bbox="1170 422 1382 464">DON'T KNOW</th> </tr> </thead> <tbody> <tr> <td data-bbox="337 464 943 506">1. Intussusception</td> <td data-bbox="943 464 1062 506">01</td> <td data-bbox="1062 464 1170 506">00</td> <td data-bbox="1170 464 1382 506">98</td> </tr> <tr> <td data-bbox="337 506 943 548">2. Kawasaki Disease</td> <td data-bbox="943 506 1062 548">01</td> <td data-bbox="1062 506 1170 548">00</td> <td data-bbox="1170 506 1382 548">98</td> </tr> <tr> <td data-bbox="337 548 943 590">3. Thrombocytopenia</td> <td data-bbox="943 548 1062 590">01</td> <td data-bbox="1062 548 1170 590">00</td> <td data-bbox="1170 548 1382 590">98</td> </tr> <tr> <td data-bbox="337 590 943 667">4. Other serious or unexpected diagnoses (specify)</td> <td data-bbox="943 590 1062 667"></td> <td data-bbox="1062 590 1170 667"></td> <td data-bbox="1170 590 1382 667"></td> </tr> </tbody> </table> <table border="1" data-bbox="337 730 1382 1010"> <thead> <tr> <th colspan="4" data-bbox="337 730 1382 772">ii. If 'Thrombocytopenia', details</th> </tr> <tr> <th data-bbox="337 772 943 800"></th> <th data-bbox="943 772 1062 800">YES</th> <th data-bbox="1062 772 1170 800">NO</th> <th data-bbox="1170 772 1382 800">DON'T KNOW</th> </tr> </thead> <tbody> <tr> <td data-bbox="337 800 943 863">1. Clinical evidence of bleeding specify</td> <td data-bbox="943 800 1062 863">01</td> <td data-bbox="1062 800 1170 863">00</td> <td data-bbox="1170 800 1382 863">98</td> </tr> <tr> <td data-bbox="337 863 943 926">2. Platelet count &lt;150x10<sup>9</sup>/L specify</td> <td data-bbox="943 863 1062 926">01</td> <td data-bbox="1062 863 1170 926">00</td> <td data-bbox="1170 863 1382 926">98</td> </tr> <tr> <td data-bbox="337 926 943 968">3. Petechial rash</td> <td data-bbox="943 926 1062 968">01</td> <td data-bbox="1062 926 1170 968">00</td> <td data-bbox="1170 926 1382 968">98</td> </tr> <tr> <td data-bbox="337 968 943 1010">4. Thrombosis</td> <td data-bbox="943 968 1062 1010">01</td> <td data-bbox="1062 968 1170 1010">00</td> <td data-bbox="1170 968 1382 1010">98</td> </tr> </tbody> </table>	Other diagnoses (physician diagnosed)	YES	NO	DON'T KNOW	1. Intussusception	01	00	98	2. Kawasaki Disease	01	00	98	3. Thrombocytopenia	01	00	98	4. Other serious or unexpected diagnoses (specify)				ii. If 'Thrombocytopenia', details					YES	NO	DON'T KNOW	1. Clinical evidence of bleeding specify	01	00	98	2. Platelet count <150x10 <sup>9</sup> /L specify	01	00	98	3. Petechial rash	01	00	98	4. Thrombosis	01	00	98				
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55.	<p data-bbox="347 575 1370 701"><b>COVID-19 Adverse Events of Special Interest (AESI):</b> Please indicate if any of the following has been diagnosed by a physician. Signs and symptoms leading to the diagnosis of an AESI should be reported above.</p> <p data-bbox="347 737 1333 898">Details/definitions are available in the user guide (<a href="https://www.canada.ca/en/public-health/services/immunization/reporting-adverse-events-following-immunization/user-guide-completion-submission-aefi-reports.html">https://www.canada.ca/en/public-health/services/immunization/reporting-adverse-events-following-immunization/user-guide-completion-submission-aefi-reports.html</a> [COVID-19 updates underway]).</p> <table border="1"> <thead> <tr> <th data-bbox="337 936 938 968"></th> <th data-bbox="938 936 1060 968">YES</th> <th data-bbox="1060 936 1170 968">NO</th> <th data-bbox="1170 936 1382 968">DON'T KNOW</th> </tr> </thead> <tbody> <tr> <td data-bbox="337 968 938 1041">1. Vaccine-associated enhanced disease</td> <td data-bbox="938 968 1060 1041">01</td> <td data-bbox="1060 968 1170 1041">00</td> <td data-bbox="1170 968 1382 1041">98</td> </tr> <tr> <td data-bbox="337 1041 938 1115">2. Multisystem inflammatory syndrome (MIS)</td> <td data-bbox="938 1041 1060 1115">01</td> <td data-bbox="1060 1041 1170 1115">00</td> <td data-bbox="1170 1041 1382 1115">98</td> </tr> <tr> <td data-bbox="337 1115 938 1188">3. Acute respiratory distress syndrome</td> <td data-bbox="938 1115 1060 1188">01</td> <td data-bbox="1060 1115 1170 1188">00</td> <td data-bbox="1170 1115 1382 1188">98</td> </tr> <tr> <td data-bbox="337 1188 938 1377">4. Acute cardiovascular injury (microangiopathy, heart failure, stress cardiomyopathy, coronary artery disease arrhythmia, myocarditis)</td> <td data-bbox="938 1188 1060 1377">01</td> <td data-bbox="1060 1188 1170 1377">00</td> <td data-bbox="1170 1188 1382 1377">98</td> </tr> <tr> <td data-bbox="337 1377 938 1472">5. Coagulation disorder (thromboembolism, haemorrhage)</td> <td data-bbox="938 1377 1060 1472">01</td> <td data-bbox="1060 1377 1170 1472">00</td> <td data-bbox="1170 1377 1382 1472">98</td> </tr> <tr> <td data-bbox="337 1472 938 1503">6. Acute kidney injury</td> <td data-bbox="938 1472 1060 1503">01</td> <td data-bbox="1060 1472 1170 1503">00</td> <td data-bbox="1170 1472 1382 1503">98</td> </tr> <tr> <td data-bbox="337 1503 938 1535">7. Acute liver injury</td> <td data-bbox="938 1503 1060 1535">01</td> <td data-bbox="1060 1503 1170 1535">00</td> <td data-bbox="1170 1503 1382 1535">98</td> </tr> <tr> <td data-bbox="337 1535 938 1566">8. Anosmia, ageusia</td> <td data-bbox="938 1535 1060 1566">01</td> <td data-bbox="1060 1535 1170 1566">00</td> <td data-bbox="1170 1535 1382 1566">98</td> </tr> <tr> <td data-bbox="337 1566 938 1598">9. Chilblain-like lesions</td> <td data-bbox="938 1566 1060 1598">01</td> <td data-bbox="1060 1566 1170 1598">00</td> <td data-bbox="1170 1566 1382 1598">98</td> </tr> <tr> <td data-bbox="337 1598 938 1671">10. Single organ cutaneous vasculitis</td> <td data-bbox="938 1598 1060 1671">01</td> <td data-bbox="1060 1598 1170 1671">00</td> <td data-bbox="1170 1598 1382 1671">98</td> </tr> <tr> <td data-bbox="337 1671 938 1703">11. Erythema multiforme</td> <td data-bbox="938 1671 1060 1703">01</td> <td data-bbox="1060 1671 1170 1703">00</td> <td data-bbox="1170 1671 1382 1703">98</td> </tr> <tr> <td data-bbox="337 1703 938 1734">12. Meningoencephalitis</td> <td data-bbox="938 1703 1060 1734">01</td> <td data-bbox="1060 1703 1170 1734">00</td> <td data-bbox="1170 1703 1382 1734">98</td> </tr> <tr> <td data-bbox="337 1734 938 1808">13. Acute disseminated encephalomyelitis</td> <td data-bbox="938 1734 1060 1808">01</td> <td data-bbox="1060 1734 1170 1808">00</td> <td data-bbox="1170 1734 1382 1808">98</td> </tr> <tr> <td data-bbox="337 1808 938 1839">14. Subacute thyroiditis</td> <td data-bbox="938 1808 1060 1839">01</td> <td data-bbox="1060 1808 1170 1839">00</td> <td data-bbox="1170 1808 1382 1839">98</td> </tr> <tr> <td data-bbox="337 1839 938 1871">15. Acute pancreatitis</td> <td data-bbox="938 1839 1060 1871">01</td> <td data-bbox="1060 1839 1170 1871">00</td> <td data-bbox="1170 1839 1382 1871">98</td> </tr> </tbody> </table>		YES	NO	DON'T KNOW	1. Vaccine-associated enhanced disease	01	00	98	2. Multisystem inflammatory syndrome (MIS)	01	00	98	3. Acute respiratory distress syndrome	01	00	98	4. Acute cardiovascular injury (microangiopathy, heart failure, stress cardiomyopathy, coronary artery disease arrhythmia, myocarditis)	01	00	98	5. Coagulation disorder (thromboembolism, haemorrhage)	01	00	98	6. Acute kidney injury	01	00	98	7. Acute liver injury	01	00	98	8. Anosmia, ageusia	01	00	98	9. Chilblain-like lesions	01	00	98	10. Single organ cutaneous vasculitis	01	00	98	11. Erythema multiforme	01	00	98	12. Meningoencephalitis	01	00	98	13. Acute disseminated encephalomyelitis	01	00	98	14. Subacute thyroiditis	01	00	98	15. Acute pancreatitis	01	00	98
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18. Acute aseptic arthritis	01	00	98														
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<b>auto</b>	<b>If YES to ANY of questions 51-55:</b>																
56.	<p>Highest impact of AEFI: (If more than one symptom, the most serious.)</p> <p>DID NOT INTERFERE WITH DAILY ACTIVITIES .....00  INTERFERED WITH BUT DID NOT PREVENT  DAILY ACTIVITIES .....01  PREVENTED DAILY ACTIVITIES .....02  DON'T KNOW .....98</p>																
57.	<p>a. Outcome at time of report:</p> <p>FULLY RECOVERED ..... 00  NOT YET RECOVERED ..... 01  PERMANENT DISABILITY/INCAPACITY ..... 02  DEATH ..... 03  DON'T KNOW ..... 98</p> <p>b. If 'DEATH', date</p> <p>___ ___ / ___ ___ / ___ ___  YR MM DD</p>																
58.	<p>Highest level of care obtained:</p> <p>NONE ..... 00  TELEPHONE/VIRTUAL CONSULTATION WITH  A HEALTH PROFESSIONAL ..... 01  NON-URGENT VISIT ..... 02  EMERGENCY VISIT ..... 03  REQUIRED HOSPITALIZATION ..... 04  RESULTED IN PROLONGATION OF EXISTING  HOSPITALIZATION ..... 05  DON'T KNOW ..... 98</p>																