**Introduction**

This standardized Case Report Form (CRF) is part of a suite of data collection tools for ZIKV infection that has been created by ISARIC.

**DESIGN OF THIS CASE REPORT FORM (CRF)**

For returning travellers there are FOUR sets of Case Report Forms (CRFs) that may be used in combination – “Returning Traveller Baseline and Outcome” (TBO), “Returning Traveller Acute Symptoms” (TAS), “Returning Traveller Laboratory Results” (TLR) and “Returning Traveller Intensive Care” (TIC).

These CRFs are to be used at enrolment, for the non-pregnant returning traveller (adult or child) who has visited a country affected by the current Zika virus (ZIKV) outbreak within 15 days of onset of symptoms.

If the patient is pregnant or a neonate complete the ZIKV Maternal and Neonate Case Report Forms respectively.

If the patient has acquired ZIKV due to sexual contact with a traveller, please refer to the Adult and Child collection of CRFs.

For additional Demographic and Epidemiological data fields, please refer to the ZIKV Demographics and Epidemiology CRF.

For all studies, we recommend completing a minimum of the **Returning Traveller Baseline and Outcome (TBO)** CRF, followed by **Returning Traveller Laboratory Results (TLR)** CRF. If the patient is admitted to an Intensive Care Unit or High Dependency Care Unit, complete **Returning Traveller Intensive Care (TIC)** CRF.

For travellers presenting with acute symptoms, complete **Returning Traveller Acute Symptoms (TAS).**

**HOW TO USE THIS CRF**

When completing the CRF modules, please note that:

* The patient or consultee/guardian/representative has been given information about the study and the informed consent form has been completed and signed.
* The study ID codes have been assigned as per hospital protocol and guidelines.
* The study ID codes have been filled in on all pages of paper CRF forms, all information should be kept confidential at all times, and identifiable information should not be recorded on the CRFs.
* Patients’ hospital ID and contact details are recorded on a separate contact list to allow later follow up. This information must be kept separate from the CRFs at all times and kept in a secure location.

Each site may choose which data to collect based on available resources and the number of patients enrolled to date. The decision is up to the site Investigators and may be changed throughout the data collection period.

**GENERAL GUIDANCE**

* We recommend writing clearly in black or blue ink, using BLOCK-CAPITAL LETTERS.
* Do NOT leave sections blank, except for where the instructions say to skip a section based on certain responses.
* The CRF is designed to collect data obtained through patient examination and chart review.
* Patient ID codes should be filled in on all pages of paper CRF forms.
* Selections with square boxes (**☐**) are single selection answers (choose one answer only). Selections with circles (**○**) are multiple selection answers (choose as many answers as are applicable).
* IMPORTANT: Please mark the ‘Unknown’ box if the answer to a particular question is not known. **Do not leave these sections blank.**
* Some sections have blank areas where you can write additional information. To permit standardized data entry, please avoid writing additional information outside of these areas.
* Place an (X) when you choose the corresponding answer. To make corrections, strike through (----) the data you wish to delete and write the correct data above it. Please initial and date all corrections.
* Please keep all of the sheets for a single patient together e.g. with a staple or in a folder that is unique to the patient.
* Please contact us if we can help with any CRF completion questions, or if you have comments and to let us know that you are using the forms. Please contact Dr Gail Carson by email: gail.carson@ndm.ox.ac.uk

**Disclaimer:** These CRFs are intended for use as a standardized document for the collection of clinical data in studies investigating ZIKV. Responsibility for use of these CRFs rests with the study investigators. ISARIC and the authors of the CRF accept no responsibility for the use of the CRF in an amended format nor for the use of the standardized CRF outside its intended purpose. *Formatting issues are in the process of being resolved. Word documents are available in order to adapt and translate the CRFs, however, there may be issues between Macs and PCs. The PDF format is also available, which should be well formatted on both operating systems*.

**INCLUSION CRITERIA**

**Define as appropriate e.g. non-pregnant returning traveller, who has visited a country affected by the current Zika outbreak within 15 days of onset of symptoms.**

**If pregnant, refer to the ZIKV Maternal and Neonate Case Report forms.**

**CONSENT**

**Ensure informed consent.**

|  |
| --- |
| **Date and time of consent (dd/mm/yyyy):** \_\_ \_\_ / \_\_ \_\_ / \_20\_ \_\_ \_\_ Time: \_\_ \_\_: \_\_ \_\_hours |
|  |
| **Name and role of the person taking consent :**  |
| **Signature of person taking consent:**  |

|  |  |  |
| --- | --- | --- |
| 1. **Geoposition**
 | Latitude: \_\_\_ \_ . \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Longitude: \_\_\_ \_ . \_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 1. **Name of site/clinic/hospital**
 |  |
| **If geoposition not available:**  |
| 1. **City/town/village:**
 |  |
| 1. **Country:**
 |  |
| 1. **Date of presentation:**
 | \_\_/\_\_/ 20 \_\_ |
| 1. **Admitted to hospital**
 | **☐** Yes  **☐** No **☐** Unknown |
| 1. **If yes, date of admission (dd/mm/yyyy)**
 | \_\_ / \_\_ / 20 \_\_ | 1. **Date of discharge**
 | \_\_ / \_\_ / 20 \_\_ **☐**Unknown  |
| 1. **Name of hospital admitted to and town/city:**
 |  |
| 1. **Date of onset of first symptoms (dd/mm/yyyy)**
 | \_\_ / \_\_ / 20 \_\_ |
| **If acute symptoms complete the ZIKV Returning Traveller Acute Symptoms (TAS) CRF module as well** |

**1) DEMOGRAPHICS**

|  |  |
| --- | --- |
| 1. **Gender**
 | **☐** Male **☐** Female  **☐** Other  **☐** Does not wish to say |
| 1. **Date of birth (dd/mm/yyyy)**
 |  |
| 1. **Country of residency**
 |  |
| 1. **Town/City/Village**
 |  |
| 1. **Occupation**
 |  |
| 1. **Ethnicity (according to national guidelines)**
 |  |

**2) COUNTRIES VISITED** (< 15 days of onset of symptoms)

|  |
| --- |
| 1. **State all countries visited within 15 days before date of onset of symptoms**
 |
| **Country** | **City/town/region visited** | **Approximate first and last date** **[dd/mm/yyyy]** | **Total number of days** | **Includes overnight stay** |
|  |  | \_\_/\_\_/\_\_\_\_ to \_\_/\_\_/\_\_\_\_ |  | **☐** Yes **☐** No |
|  |  | \_\_/\_\_/\_\_\_\_ to \_\_/\_\_/\_\_\_\_ |  | **☐** Yes **☐** No |
|  |  | \_\_/\_\_/\_\_\_\_ to \_\_/\_\_/\_\_\_\_ |  | **☐** Yes **☐** No |
|  |  | \_\_/\_\_/\_\_\_\_ to \_\_/\_\_/\_\_\_\_ |  | **☐** Yes **☐** No |
|  |  | \_\_/\_\_/\_\_\_\_ to \_\_/\_\_/\_\_\_\_ |  | **☐** Yes **☐** No |
|  |  | \_\_/\_\_/\_\_\_\_ to \_\_/\_\_/\_\_\_\_ |  | **☐** Yes **☐** No |

**3) RISK FACTORS**

|  |  |  |  |
| --- | --- | --- | --- |
| 1. **Has the patient received a blood transfusion?**
 | **☐**Yes**☐**No **☐**Unknown | **Specify/estimate date of last blood transfusion** **☐**<30 days ago**☐**>30 days ago | **Reason for transfusion:****\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
| 1. **Does the patient or their partner use any form of sexual protection?**
 | **☐**YES **☐**No **☐**Unknown **☐**Not applicable  | **If yes, which methods?** | **○** None**○** Condoms (male/female)**○** Diaphragm/Cap**○** Dental dam**○** Gloves**○** Other (specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**○** Does not wish to say |
| 1. **Tobacco use?**
 | **☐**Yes **☐**No **☐**Unknown | **If yes, specify average per day:****☐** <10 cigarettes per day**☐** ≥10 cigarettes per day | **☐** Other forms of smoking/tobaccoSpecify: |
| 1. **Alcohol consu mption?**
 | **☐**Yes **☐**No **☐**Unknown | **If yes, specify average alcohol consumption per day****☐** Less than 1-2 alcoholic drinks[[1]](#footnote-1) per day**☐** 2-5 alcoholic drinks per day**☐** >5 alcoholic drinks per day | **Specify type\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |

Note: If further demographic or epidemiology information is required please use a complementary ZIKV CRF Demographics and Epidemiology

**4) CO-MORBIDITIES** (existing PRIOR TO ADMISSION & which are active problems)

|  |  |
| --- | --- |
| 1. **Chronic cardiovascular disease**[[2]](#footnote-2)
 | **☐**Yes **☐**No **☐**Unknown |
| 1. **Chronic pulmonary disease**[[3]](#footnote-3)
 | **☐**Yes **☐**No **☐**Unknown |
| 1. **Blood disorders**
 | **☐**Yes **☐**No **☐**Unknown |
| ***If yes, please specify:*** |
| 1. **Chronic renal/kidney disease**[[4]](#footnote-4)
 | **☐**Yes **☐**No **☐**Unknown |
| 1. **Chronic liver disease – moderate or severe**[[5]](#footnote-5)
 | **☐**Yes **☐**No **☐**Unknown |
| 1. **Chronic neurological disease**[[6]](#footnote-6)
 | **☐**Yes **☐**No **☐**Unknown |
| ***If yes, please specify:*** |
| 1. **Paralysis**
 | **☐**Yes **☐**No **☐**Unknown |
| ***If yes, please specify body parts affected:*** |
| 1. **Type 1 Diabetes**
 | **☐**Yes **☐**No **☐**Unknown |
| 1. **Type 2 Diabetes and treated with oral medicine or insulin dependent**
 | **☐**Yes **☐**No **☐**Unknown |
| 1. **Other endocrine disease**[[7]](#footnote-7)
 | **☐**Yes **☐**No **☐**Unknown |
| ***If yes, please specify:*** |  |
| 1. **Rheumatologic disease**[[8]](#footnote-8)
 | **☐**Yes **☐**No **☐**Unknown |
| 1. **HIV**[[9]](#footnote-9)
 | **☐**Yes **☐**No **☐**Unknown |
| ***If yes, on antiretroviral therapy?*** | **☐**Yes **☐**No **☐**Unknown |
| 1. **CD4 cell count**
 | **☐** <200 cells/µL **☐**200-499 cells/µL **☐** ≥500 cells/µL **☐**Unknown |
| 1. **Other immunosuppression?**
 | **☐**Yes **☐**No **☐**Unknown |
| ***If yes, please specify:*** |  |
| 1. **Any other chronic comorbidity (please specify):**
 | **☐**Yes **☐**No **☐**Unknown |

**5) IMMUNISATION HISTORY**

|  |  |  |  |
| --- | --- | --- | --- |
| **Vaccine** | **Immunized** | **Estimate date of last dose** (mm/yyyy) or age | **Course completed** |
| 1. **Yellow fever\***
 | **☐**Yes **☐**No **☐**Unknown |  | **☐**Yes **☐**No **☐**Unknown |
| 1. **Japanese encephalitis\***
 | **☐**Yes **☐**No **☐**Unknown |  | **☐**Yes **☐**No **☐**Unknown |
| 1. **Tick-borne encephalitis\***
 | **☐**Yes **☐**No **☐**Unknown |  | **☐**Yes **☐**No **☐**Unknown |
| 1. **Dengue virus**
 | **☐**Yes **☐**No **☐**Unknown |  | **☐**Yes **☐**No **☐**Unknown |

\**These vaccinations may cross-react with ZIKV serology*

**6) PREVIOUS ARBOVIRUS INFECTIONS**

|  |  |  |  |
| --- | --- | --- | --- |
| **Arbovirus** |  | **Estimated date of onset** (mm/yyyy): | **Certainty** |
| 1. **Dengue fever**
 | **☐**YES **☐**NO **☐**Unknown | \_\_/\_\_\_\_ | **☐**Lab. confirmed**☐**Medical records**☐**Self-reported |
| 1. **Japanese encephalitis**
 | **☐**YES **☐**NO **☐**Unknown | \_\_/\_\_\_\_ | **☐**Lab. confirmed**☐**Medical records**☐**Self-reported |
| 1. **St. Louis encephalitis**
 | **☐**YES **☐**NO **☐**Unknown | \_\_/\_\_\_\_ | **☐**Lab. confirmed**☐**Medical records**☐**Self-reported |
| 1. **West Nile virus**
 | **☐**YES **☐**NO **☐**Unknown | \_\_/\_\_\_\_ | **☐**Lab. confirmed**☐**Medical records**☐**Self-reported |
| 1. **Tick-borne encephalitis**
 | **☐**YES **☐**NO **☐**Unknown | \_\_/\_\_\_\_ | **☐**Lab. confirmed**☐**Medical records**☐**Self-reported |
| 1. **Chikungunya**
 | **☐**YES **☐**NO **☐**Unknown | \_\_/\_\_\_\_ | **☐**Lab. confirmed**☐**Medical records**☐**Self-reported |
| 1. **Yellow fever**
 | **☐**YES **☐**NO **☐**Unknown | \_\_/\_\_\_\_ | **☐**Lab. confirmed**☐**Medical records**☐**Self-reported |
| 1. **Other (specify):**
 |  | \_\_/\_\_\_\_ | **☐**Lab. confirmed**☐**Medical records**☐**Self-reported |

**7) BASELINE OBSERVATIONS** (≤ 24 hours of admission)

|  |
| --- |
| **BASELINE OBSERVATIONS**  |
| 1. **Date (dd/mm/yyyy)**
 | \_\_ / \_\_ / 20 \_\_ \_\_ |
| 1. **Maximum Temperature**
 | \_\_\_\_\_\_°C **☐** \_\_\_\_\_\_°F **☐ ☐** Unknown**☐**Oral **☐**Tympanic **☐**Axillary **☐**Anal **☐**Skin |
| 1. **Respiratory Rate**
 |  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_breaths/minute **☐** Unknown |
| 1. **Heart Rate**
 | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ beats/minute **☐** Unknown |
| 1. **Systolic Blood Pressure**
 | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_mmHg **☐** Unknown |
| 1. **Diastolic Blood Pressure**
 | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_mmHg **☐** Unknown |
| 1. **Peripheral O2 Saturation (SpO2)**
 | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ % **☐** Unknown |
| 1. **Glasgow Coma Score (out of 15) or**
 | \_\_\_ / 15 **☐** Unknown |
| 1. **AVPU (tick state of consciousness)**
 | ☐Alert ☐Responds to verbal stimuli ☐ Responds to pain stimuli ☐ Unresponsive |
| 1. **Weight**
 | \_\_\_\_\_\_\_\_\_\_\_\_\_ ☐kg ☐pounds/ounces  |
| 1. **Height**
 | \_\_\_\_\_\_\_\_\_\_\_\_\_\_ ☐cm ☐feet/inches  |
| 1. **Weight loss**
 | ☐Yes ☐No ☐Unknown |
| **If yes, specify lost during this current episode of illness** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_ ☐kg ☐pounds/ounces  |
| 1. **Lymphadenopathy**
 | **☐**Cervical only **☐**General **☐**No **☐**Unknown |
| 1. **Enlarged liver**
 | ☐Yes ☐No ☐Unknown | 1. **Enlarged spleen**
 | ☐Yes ☐No ☐Unknown |

**8) SYMPTOMS** (since first day of onset of this illness episode)

|  |  |
| --- | --- |
| 1. **Amnesia**
 | ☐Yes ☐No ☐Unknown |
| 1. **Confusion/disorientation**
 | ☐Yes ☐No ☐Unknown |
| 1. **Altered behavior or personality**
 | ☐Yes ☐No ☐Unknown |
| 1. **Headache**
 | **☐**Mild **☐**Moderate **☐**Severe **☐**No **☐**Unknown |
| 1. **Photophobia**
 | **☐**Yes **☐**No **☐**Unknown |
| 1. **Neck stiffness**
 | **☐**Yes **☐**No **☐**Unknown |
| 1. **Seizures**
 | **☐**General **☐**Focal **☐**No **☐**Unknown |
| 1. **Paralysis**
 | **☐**General **☐**Ascending **☐**No **☐**Unknown |
| **If yes, please describe affected body parts and if progressive: ☐yes ☐no** |
| 1. **Weakness**
 | **☐**General **☐**Focal **☐**No **☐**Unknown**○**Power test **○**Patient complaint |
| **If focal, please describe affected body parts and if progressive: ☐yes\* ☐no**  |
| 1. **Oromotor dysfunction**
 | **☐**Yes **☐**No **☐**Unknown |
| 1. **Movement disorder**
 | **☐**Yes **☐**No **☐**Unknown |
| 1. **Shortness of breath**
 | **☐**Yes **☐**No **☐**Unknown |
| 1. **Sore throat**
 | **☐**Yes **☐**No **☐**Unknown |
| 1. **Cough**
 | **☐**Yes **☐**No **☐**Unknown |
| 1. **Rhinitis**
 | **☐**Yes **☐**No **☐**Unknown |
| 1. **Chest pain**
 | **☐**Yes **☐**No **☐**Unknown |
| 1. **Back pain**
 | **☐**Yes **☐**No **☐**Unknown |
| 1. **Myalgia**
 | **☐**Yes **☐**No **☐**Unknown |
| 1. **Arthralgia**
 | **☐**Yes **☐**No **☐**Unknown |
| 1. **Joint swelling**
 | **☐**Yes **☐**No **☐**Unknown |
| **If yes, specify all affected joints:** | **○** Fingers **○** Toes **○** Knee **○** Elbow  **○** Other **(**specify):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 1. **Conjunctivitis**
 | **☐**Yes **☐**No **☐**Unknown |
|  **If yes, specify if:** | **☐**Purulent **☐**Non-purulent |
| 1. **Retro-orbital pain**
 | **☐**Yes **☐**No **☐**Unknown |
| 1. **Periorbital pain**
 | **☐**Yes **☐**No **☐**Unknown |
| 1. **Rash**
 | **☐**Yes **☐**No **☐**Unknown |
| **If yes, please check box for type of rash and specify location:** | **Spread of the rash:** |
| 1. **Maculopapular rash**
 | **☐**Yes **☐**No  | **☐**Centrifugal **☐**Centripetal Location:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 1. **Erythematous rash**
 | **☐**Yes **☐**No  | **☐**Centrifugal **☐**Centripetal Location:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 1. **Non blanching rash**
 | **☐**Yes **☐**No  | **☐**Centrifugal **☐**Centripetal Location:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 1. **Vesicular rash**
 | **☐**Yes **☐**No  | **☐**Centrifugal **☐**Centripetal Location:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 1. **Erythema migrans**
 | **☐**Yes **☐**No  | **☐**Centrifugal **☐**Centripetal Location:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 1. **Pruritic rash**
 | **☐**Yes **☐**No  | **☐**Centrifugal **☐**Centripetal Location:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 1. **Petechial or purpuric rash**
 | **☐**Yes **☐**No  | **☐**Centrifugal **☐**Centripetal Location:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 1. **Bruising/ ecchymosis**
 | **☐**Yes **☐**No  | **☐**Centrifugal **☐**Centripetal Location:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 1. **If other type of rash, please specify type and spread:**
 | Type:⭘Face ⭘Torso ⭘Upper limbs ⭘Lower limbs ⭘Palms ⭘ Other: |
| 1. **Pruritus**
 | **☐**Yes **☐**No **☐**Unknown |
| **If yes, specify:** | **☐** Generalized **☐** Localized |
| 1. **Jaundice**
 | **☐**Yes **☐**No **☐**Unknown |
| 1. **Sign of insect bites**
 | **☐**Yes **☐**No **☐**Unknown |
| 1. **Bleeding**
 | **☐**Yes **☐**No **☐**Unknown |
| **If yes, please state source:** | ⭘ Bruising ⭘ Gums ⭘ Nose ⭘ Hematemesis ⭘ Melena or fresh per rectum ⭘ Hematuria ⭘ Vaginal ⭘ Other, specify: |
| 1. **Mouth ulcers**
 | **☐**Yes **☐**No **☐**Unknown |
| 1. **Diarrhea**
 | **☐**Yes **☐**No **☐**Unknown |
| 1. **Vomiting/nausea**
 | **☐**Yes **☐**No **☐**Unknown |
| 1. **Stomach pain**
 | **☐**Yes **☐**No **☐**Unknown |

**\*** ***If GBS like symptoms identified, please refer to specific GBS or ZIKV neurological studies.***

**9) MEDICATIONS ADMINISTERED** (from onset of first symptoms of this illness episode) Please list **all** medications taken by the patient during this episode, including antibiotics, antivirals and other regular medications, including herbal, and non-licensed remedies. Please list generic names if possible.

|  |
| --- |
| **List all medications administered for acute symptoms:** **Use generic names**, list all treatment given for this illness episode from date of onset. |
|  **Type of medication** | **Name of medication and doce**(generic name ) | **Start date** (dd/mm/yyyy) | **Number of days duration**  | **Route of administration** |
| 1. **Antibiotics**

**☐**Yes **☐**No  |  |  |  | **☐**IV **☐**Oral **☐**IM  |
| 1. **Antivirals**

**☐**Yes **☐**No  |  |  |  | **☐**IV **☐**Oral  |
| 1. **Corticosteroids**

**☐**Yes **☐**No  |  |  |  | **☐**IV **☐**Oral **☐**Topical **☐**Inhaled |
| 1. **Anti-inflammatory or Antipyretic**

**☐**Yes **☐**No  |  |  |  | **☐**IV **☐**Oral  |
| 1. **Immunoglobulins**

**☐**Yes **☐**No  |  |  |  | **☐**IV **☐**Oral **☐** Other, detail: |
| 1. **Other (specify):**
 |  |  |  | **☐**IV **☐**Oral **☐** Other, detail: |
| **Other (specify):** |  |  |  | **☐**IV **☐**Oral **☐** Other, detail: |
| **Other (specify):** |  |  |  | **☐**IV **☐**Oral **☐** Other, detail: |
| **Other (specify):** |  |  |  | **☐**IV **☐**Oral **☐** Other, detail: |

**10) IMAGING** (if available as part of routine care.)

If abnormal, please describe abnormality and enclose images if possible.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Neuroimaging** | **Results** | **If abnormal, please summarize key results from report:** | **Images attached** | **Report attached** |
| 1. **CT**
 | **☐**Normal **☐**Abnormal **☐**Not Done |  | **☐**Yes**☐**No | **☐**Yes**☐**No |
| 1. **MRI**
 | **☐**Normal **☐**Abnormal **☐**Not Done |  | **☐**Yes**☐**No | **☐**Yes**☐**No |
| 1. **EEG**
 | **☐**Normal **☐**Abnormal **☐**Not Done |  | **☐**Yes**☐**No | **☐**Yes**☐**No |
| 1. **Other (specify type of test):**
 | **☐**Normal **☐**Abnormal  |  | **☐**Yes**☐**No | **☐**Yes**☐**No |

**11) DIAGNOSTIC OUTCOMES**

Record final diagnostics outcomes based on local/regional laboratory results, clinical presentation and case definitions. Please choose the appropriate case definition, e.g. WHO or national/local case definition and ensure the definition used is clear and shared with all involved in the study.

|  |  |  |  |
| --- | --- | --- | --- |
| **Pathogen** | **Diagnosis** | **Date of onset** (dd/mm/yyyy) | **Comment** |
| 1. **No confirmed diagnosis**
 | **☐**Tick if no diagnosis made |  |  |
| 1. **Zika virus**
 | **☐** Confirmed acute infection**☐**Probable acute infection**☐**Confirmed past infection**☐**Probable past infection**☐**Negative **☐**Not tested **☐**Unknown | \_\_/\_\_/20\_\_ |  |
| 1. **Dengue virus**
 | **☐** Confirmed acute infection**☐**Probable acute infection**☐**Confirmed past infection**☐**Probable past infection**☐**Negative **☐**Not tested **☐**Unknown | \_\_/\_\_/20\_\_ |  |
| 1. **Chikungunya virus**
 | **☐** Confirmed acute infection**☐**Probable acute infection**☐**Confirmed past infection**☐**Probable past infection**☐**Negative **☐**Not tested **☐**Unknown | \_\_/\_\_/20\_\_ |  |
| 1. **West Nile virus**
 | **☐** Confirmed acute infection**☐**Probable acute infection **☐**Confirmed past infection**☐**Probable past infection**☐**Negative **☐**Not tested **☐**Unknown  | \_\_/\_\_/20\_\_ |  |
| 1. **Yellow fever virus**
 | **☐** Confirmed acute infection**☐**Probable acute infection **☐**Confirmed past infection**☐**Probable past infection**☐**Negative **☐**Not tested **☐**Unknown  | \_\_/\_\_/20\_\_ |  |
| 1. **Malaria**
 | **☐**Confirmed acute infection**☐**Probable acute infection**☐**Negative **☐**Not tested **☐**Unknown | \_\_/\_\_/20\_\_ |  |
| 1. **Other (specify):**
 | **☐**Confirmed acute infection**☐**Probable acute infection**☐**Confirmed past infection**☐**Probable past infection**☐**Negative  | \_\_/\_\_/20\_\_ |  |
| **Other (specify):** | **☐** Confirmed acute infection**☐**Probable acute infection**☐**Confirmed past infection**☐**Probable past infection**☐**Negative  | \_\_/\_\_/20\_\_ |  |

**12) OUTCOME** (Complete at discharge/going home or death)

|  |  |
| --- | --- |
| **Outcome** | **Details** |
| 1. **Date of discharge/going home [dd/mm/yyyy]**
 | \_\_ / \_\_ / 20\_\_ |
| 1. **Outcome at discharge/going home**
 | **☐**Discharged/sent home without sequelae **☐**Discharged/ sent home with sequelae **☐**Deceased ☐Unknown |
| 1. **If discharged/ sent home with sequelae, describe:**
 |  |
| 1. **If deceased, specify date of death [dd/mm/yyyy]**
 | \_\_ / \_\_\_ / \_\_\_\_\_\_\_\_ |
| 1. **Zika virus infection**
 | **☐**Positive **☐**Probable**☐**Negative **☐**Unknown **☐**Not tested |
| 1. **Diagnosis confirmed by:**
 | **☐**Lab. confirmed (local hospital laboratory) **☐**Lab. confirmed (national reference laboratory) **☐**Lab. confirmed (international reference laboratory) **☐**Other, please detail: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  |
| 1. **Any other outcome, specify all:**
 |
| 1. **Was autopsy performed?**
 | **☐**Yes **☐**No **☐**Unknown |
|  **If yes, please specify autopsy results:** |  |

**13) CASE REPORT COMPLETED BY**

|  |  |
| --- | --- |
|  **Name and role** |  |
|  **Signature** |  | **Date** (dd/mm/yyyy) | \_\_ / \_\_\_/ 20 **\_\_\_\_** |

1. A drink is defined as any alcoholic drink for example a glass of wine, a glass of beer, a cocktail [↑](#footnote-ref-1)
2. Includes coronary heart disease, cerebrovascular disease (stroke), hypertension (Diastolic > 100mm/Hg), peripheral artery disease, rheumatic heart disease, congenital heart disease and heart failure. www.who.int/topics/cardiovascular\_diseases/en/ [↑](#footnote-ref-2)
3. Chronic lung diseases that cause limitations in lung airflow (previously referred to as emphysema, chronic bronchitis), diagnosed by spirometry or clinical signs e.g. abnormal shortness of breath and increased forced expiratory time. www.who.int/respiratory/copd/diagnosis/en/ [↑](#footnote-ref-3)
4. Creatinine >3mg% (265 μmol/l), dialysis, transplantation, uremic syndrome [↑](#footnote-ref-4)
5. Cirrhosis with PHT +/- variceal bleeding [↑](#footnote-ref-5)
6. Disorders of the nervous system e.g. epilepsy, MS, Parkinson, chronic pain syndromes, chronic brain injuries, ALS etc. [↑](#footnote-ref-6)
7. Hypopituitarism, adrenal insufficiency, recurrent acidosis [↑](#footnote-ref-7)
8. SLE, polymyositis, polymyalgia rheumatic, mixed connective tissue diseases [↑](#footnote-ref-8)
9. Laboratory-confirmed HIV-1 or HIV-2 infection (irrespective of the CD4 lymphocyte count/percentage or HIV viral load in blood), or a patient with an AIDS-defining condition. [↑](#footnote-ref-9)