***Insert trial title*\_**\_ CRF Database Validation Checks

**Key**

***Question #*** - number on the CRF

***Question text*** – data point description as per CRF

***CDASH code*** – data point CDISC - CDASH variable name

***Type –*** Type of question e.g. category or integer etc.

***Value –*** eg. Yes/No/N/A or mmol & mg/L etc.

***Level*** – if this question is related to the previous question

***Blinded –*** Option for the question to be blind depending on the answer to the previous question. (i.e. If answered NO to ICU admission the rest of the ICU module does not appear).

***Null allowed*** – No = mandatory field that needs to be answered, Yes = can be left blank (this can be used in conjunction with the blinded option).

***Range*** – The range we will allow people to enter (e.g. glucose (IF mmol/L checked: min= 3.9mmol/L max = 20mmol/L \* if mg/dL checked: min = 70 mg/dL max = 360 mg/dL)

**Notes** – comments or questions you have about the data point / logical check ranges.

**Comments**:

* Enforce the use of units when entering specific values.
* Place restrictions on extreme values.
* Date of Birth - year accept any value.
* All the repeated variables are coded the same in all the sheets. It would be helpful if the sheet name could be added to the code in the data extraction.
* Pathogen Testing CRF - only for positive results but in the previous database we indicated any tested results.
* Medication CRF - it would be preferable if antiviral, antibiotic, antifungal, corticosteroids and other medication could be in separate data tables.
* The Admin user has authority to keep mandatory fields blank.

| **Question #** | **Question Text** | | **CDASH Variable Name** | **Type** | **Value** | **Level** | **Blinded** | **Null allowed** | **Range Check** | **Other checks** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Must answer YES to the following two questions for the patient to be eligible** | | | | | | | | | |
| 1.0 | **Suspected or proven acute respiratory infection** | | IEORRES  IEOCCUR | Category | Yes/No | 0 | No | No |  | WARN and REJECT IF  IEOCCUR = No  MSG – This question must be answered as YES |
| 1.1 | **New admission with symptom onset within the previous 14 days** | | IEORRES  IEOCCUR | Category | Yes/No | 0 | No | no |  | WARN and REJECT IF  IEOCCUR = No  MSG – This question must be answered as YES |
|  | **Must answer YES to at least one of the following** **questions for the patient to be eligible** | | | | | | | | | |
|  |  | **Experience of the following symptoms during this illness episode** | | | | | | | | |
| 1.2 | **A history of feverishness or measured fever of ≥ 38oC** | | IEORRES  IECOCCUR1 | Category | Yes/No | 0 | No | No |  |  |
| 1.3 | **Cough** | | IEORRES  IEOCCUR2 | Category | Yes/No | 0 | No | No |  | WARN AND REJECT IF IEOCCUR2 = No AND IEOCCUR1 = No AND IEOCCUR2 = No  MSG – At least one of the following questions must answered as YES |
| 1.4 | **Dyspnoea (shortness of breath) OR Tachypnoea** | | IEORRES  IEOCCUR3 | Category | Yes/No | 0 | No | No |  | WARN AND REJECT IF IEOCCUR3 = No AND IEOCCUR1 = No AND IEOCCUR2 = No  MSG – At least one of the following questions must answered as YES |

|  | |  | |  |  |  |  |  |  |  |  | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | |  | |  |  |  |  |  |  |  |  | |
| **RAPID CRF** | | | |  |  |  |  |  |  |  |  | |
|  | |  | |  |  |  |  |  |  |  |  | |
| **Question #** | | **Question Text** | | **CDASH Variable Name** | **Type** | **Value** | **Level** | **Blinded** | **Null allowed** | **Range Check** | **Other checks** | |
|  | Section 1. Site | | | | | | | | | |
| 1.0 | | **Clinical Centre Name** | | SITEID | Free text |  | 0 | No | No |  |  | |
| 1.1 | | **Country** | | COUNTRY | Free text |  | 0 | No | no |  |  | |
| 1.2 | | **Enrolment date** | | ENRLDAT | Date/Time DD/MM/YYYY |  | 0 | No | NO |  |  | |
|  |  | |  | | | | | | | | | |
| 2.0 | | **Sex at birth** | | SEX | Category | male / female | 0 | No | No |  |  | |
| 2.1 | | **Date of birth** | | BRTHDAT | Date/Time DD/MM/YYYY |  | 0 | No | yes |  | WARN and  REJECT IF BRTHDAT > than now  MSG – This date is in the future | |
| 2.2 | | **If unknown, Estimated age years** | | AGE | Integer  999 |  | 0 | No | No |  | COLLECT IF BRTHDAT = Unknown (UK) AND enforce no null allowed | |
|  | | **If unknown, estimated age in months** | | AGEU | Integer | Years or months |  | No | no |  | COLLECT IF BRTHDAT = Unknown (UK) AND enforce no null allowed | |
| 2.3 | | **Pregnant** | | SCORRES | Category | Yes/No/Unknown/N/A | 0 | No | no |  |  | |
| 2.4 | | **If Yes, Gestational weeks assessment** | | SCORRESU | Integer  99 | [][] weeks | 0 | No | If yes 2.4, pregnant. No null allowed |  | COLLECT IF SCORRES = Yes Unknown (UK) AND enforce no null allowed | |
|  | Section 3. Onset & Admission | | | | | | | | | | |
| 3.0 | | **Onset date of first/earliest symptom** | | CESTDAT | Date/Time DD/MM/YYYY |  | 0 | No | no |  | WARN and REJECT IF CESTDAT > than now  MSG – This date is in the future | |
| 3.1 | | **Admission date at this facility** | | HOSTDAT | Date/Time DD/MM/YYYY |  | 0 | No | No | Date same or less than 3.1 date of symptom onset | WARN and REJECT IF HOSTDAT < CESTDAT  MSG – This date is before onset date of first/earliest symptom | |
|  | Section 4. ICU OR HDU ADMISSION | | | | | | | | | | |
| 4.0 | | **Admitted to ICU** | | HOSTPERF | Category | Yes / No | 0 | No | No |  |  | |
| 4.1 | | **First ICU admission date** | | HOSTDTC | Date/Time | DD/MM/YYYY | 1 | Yes, if 4.1 selected all questions until section 5 appear | If yes 4.1, no null allowed (same for all below in ICU section 4.) |  | WARN IF HOSTDTC is > than now  MSG – This date is in the future  REJECT IF HOSTDTC  < HOSTDAT  MSG – This date is before the admission date at this facility | |
| 4.1.1 | | **Mechanical ventilation** | | PRTRT  PRPERF | Category | Yes / No/N/A | 1 | Yes, if 4.1 selected all questions until section 5 appear | If yes 4.1, no null allowed (same for all below in ICU section 4.) |  | COLLECT IF HOSPERF = Yes AND enforce no null allowed | |
| 4.1.2 | | **FiO2** | | LBTEST  LBORRES  LBORRESU | Real  99 or 9.99 | L/min |  | Yes, if 4.1 selected all questions until section 5 appear | If yes 4.1, no null allowed (same for all below in ICU section 4.) |  | COLLECT IF HOSPERF = Yes AND enforce no null allowed | |
| 4.1.3 | | **Sa02** | | LBTEST  LBORRES  LBORRESU | Integer  999 | % | 1 | Yes, if 4.1 selected all questions until section 5 appear | If yes 4.1, no null allowed (same for all below in ICU section 4.) |  | COLLECT IF HOSPERF = Yes AND enforce no null allowed | |
| 4.1.4 | | **PaO2** | | LBTEST  LBORRES  LBORRESU | Integer  999  Category | kPa or mmHg | 1 | Yes, if 4.1 selected all questions until section 5 appear | If yes 4.1, no null allowed (same for all below in ICU section 4.) |  | COLLECT IF HOSPERF = Yes AND enforce no null allowed AND units | |
| 4.1.5 | | **Platelet count** | | LBTEST  LBORRES  LBORRESU | Real  999.9 | x10 9/L | 1 | Yes, if 4.1 selected all questions until section 5 appear | If yes 4.1, no null allowed (same for all below in ICU section 4.) |  | COLLECT IF HOSPERF = Yes AND enforce no null allowed | |
| 4.1.6 | | **Creatinine** | | LBTEST  LBORRES  LBORRESU | Real  9999.9  Category | µmol/L or mg/dL |  | Yes, if 4.1 selected all questions until section 5 appear | If yes 4.1, no null allowed (same for all below in ICU section 4.) |  | COLLECT IF HOSPERF = Yes AND enforce no null allowed AND units | |
| 4.1.7 | | **Bilirubin** | | LBTEST  LBORRES  LBORRESU | Real  99.9  Category | µmol/L or mg/dL |  | Yes, if 4.1 selected all questions until section 5 appear | If yes 4.1, no null allowed (same for all below in ICU section 4.) |  | COLLECT IF HOSPERF = Yes AND enforce no null allowed AND units | |
| 4.1.8 | | **Mean arterial pressure** | | LBTEST  LBORRES  LBORRESU | Integer  999 | mmHg |  | Yes, if 4.1 selected all questions until section 5 appear | If yes 4.1, no null allowed (same for all below in ICU section 4.) |  | COLLECT IF HOSPERF = Yes AND enforce no null allowed | |
| 4.1.9 | | **Urine outputs** | | LBTEST  LBORRES  LBORRESU | Integer  9999  Category | mL/24 hours and Check if estimated |  | Yes, if 4.1 selected all questions until section 5 appear | Yes | 0 -15000 | COLLECT IF HOSPERF = Yes AND enforce no null allowed AND units  WARN and REJECT IF < =0 OR => 15000  MSG This value is out of range | |
| 4.1.10 | | **Glasgow coma scale** | | RSTEST  RSORRES | Integer  99 |  | 1 | Yes, if 4.1 selected all questions until section 5 appear | If yes 4.1, no null allowed (same for all below in ICU section 4.) | 3 - 15 | COLLECT IF HOSPERF = Yes AND enforce no null allowed  WARN and REJECT IF <3 OR > 15  MSG This value is out of range | |
| 4.2 | | **Vassopressor/Inotropic Support on 1st day of ICU/HDU admi** | | CMTRT  CMPERF | Category | Yes/No/N/A | 1 | Yes, if 4.1 selected all questions until section 5 appear | If yes 4.1, no null allowed (same for all below in ICU section 4.) |  | Collect IF HOSPERF = Yes AND enforce no null allowed | |
| 4.2.0 | | **Dopamine <5ug/kg/min** | | CMTRT  CMOCCUR1 | Category | Yes/No | 1 | Yes, if 4.3 selected 4.3.1-4.3.3 appear | If yes to 4.3, one these measures (4.3.1-4.3.3) must be entered |  | Collect IF CMPERF = Yes AND enforce no null allowed | |
| 4.2.1 | | **Dopamine <5ug/kg/min** | | CMTRT  CMOCCUR2 | Category | Yes/No | 1 | Yes, if 4.3 selected 4.3.1-4.3.3 appear |  | Collect IF CMPERF = Yes AND enforce no null allowed  WARN IF IEOCCUR2 = No AND IEOCCUR1 = No  MSG – At least one of the following questions must answered as YES | |
| 4.3.2 | | **Dopamine <5ug/kg/min** | | CMTRT  CMOCCUR3 | Category | Yes/No | 1 | Yes, if 4.3 selected 4.3.1-4.3.3 appear |  | Collect IF CMPERF = Yes AND enforce no null allowed  WARN AND REJECT IF IEOCCUR3 = No AND IEOCCUR1 = No AND IEOCCUR2 = No  MSG – At least one of the following questions must answered as YES | |
| 4.3.3 | | **Date of ICU discharge** | | HOENDTC | Date/Time DD/MM/YYYY |  | 1 | No | If yes 4.1, no null allowed (same for all below in ICU section 4.) | Date more than Date of admission to ICU | Collect IF HOSPERF = Yes AND enforce no null allowed  WARN IF HOENDTC > than now  MSG – This date is in future  REJECT IF HOENDTC = < HOSTDTC  MSG - This date is before the first ICU admission date | |
| 4.3.4 | | **Total ICU duration** | | HOSDUR  HOSDURU | Integer  999 | DAYS | 1 | No | If yes 4.1, no null allowed (same for all below in ICU section 4.) |  | Collect IF HOSPERF = Yes AND enforce no null allowed | |
|  | Section 5. Infectious Respiratory Diagnosis | | | | | | | | | | |
| 5. 0 | | **Influenza** | | FAOBJ  FAOORES | Category  Free Text | Yes – Confirmed  Yes – Probable  **If** yes: A/H3N2 or AH1N1pdm09 or A/H7N9 A/H5N1 or 3  No  Other | 0 | No | No |  |  | |
| 5.1 | | **Conavirus** | | FAOBJ  FAORRES | Category  Free Text | Yes – Confirmed  Yes – Probable  **If** yes: Mers-CoV or Other  No  Other | 0 | No | no |  |  | |
| 5.2 | | **Other** | | FAOBJ  FAORRES | Category  Free Text | Yes – Confirmed  Yes – Probable  No  If yes: Other | 0 | No | no |  |  | |
| 5.3 | | **Clinical pneumonia** | | FAOBJ  FAORRES | Category | Yes/No |  |  |  |  |  | |
| 5.4 | | **If none of the above: Unknown/non-infective** | | FAOBJ  FAORRES | Category  Free Text | Yes | 0 | No | yes |  |  | |
|  | Section 6. OUTCOME, during hospital admission did the patient at any time receive | | | | | | | | | | |
| 6.0 | | **Oxygen therapy** | | CMTRT  CMPERF | Category | Yes / No/N/A | 0 | No | no |  |  | |
| 6.1 | | **Invasive ventillation** | | PRTRT  PRPERF | Category | Yes / No/N/A | 0 | No | No |  |  | |
| 6.2 | | **Non-invasive ventillation** | | PRTRT  PRPERF | Category | Yes / No/N/A | 0 | No | No |  |
| 6.3 | | **ECMO/ECSL** | | PRTRT  PRPERF | Category | Yes / No/N/A | 0 | No | No |  |
| 6.4 | | **Dialysis** | | PRTRT  PRPERF | Category | Yes / No/N/A | 0 | No | No |  |
| 6.5 | | **Multiple ICU admission** | | PRTRT  PRPERF | Category | Yes/No/N/A | 0 | No | no |  |
| 6.6.1-6.6.5 | | **Outcome** | | SSORRES | Category | Alive at discharge/  Hospitalisation/  Transferred to other facility /Died/palliative discharge | 0 | No | No |  |
| 6.7 | | **Date of final outcome** | | SSDAT | Date/Time | DD/MM/YYYY | 0 | No | No | Date more than Date of admission to ICU | WARN IF SSDAT > than now  MSG – This date is in the future REJECT IF SSDAT IS < HOSTDAT  MSG – This date is before the admission date at this facility | |

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Module 2. DAILY LABORATORY RESULTS** | | | | | | | | | |
|  | | | | | | | | | |
| 1.0 | **Results available for samples taken on *the date in section 1 above?*** | LBPERF | Category | Yes/No | 0 | No | Yes |  |  |
| 1.1 | **Haemoglobin** | LBTEST  LBORRES  LBORRESU | Real  999.9  Category | g/L *or*g/dL | 1 | No | yes |  | Enforce Unit |
| 1.2 | **Haematocrit** | LBTEST  LBORRES  LBORRESU | Real  99 | % | 1 | No | Yes |  |  |
| 1.3 | **WBC count** | LBTEST  LBORRES  LBORRESU | Real  99.9  Category | x109/L *or*x103/µL | 1 | No | yes |  | Enforce Unit |
| 1.4 | **Platelets** | LBTEST  LBORRES  LBORRESU | Real  999.9  Category | x109/L *or*x103/µL | 1 | No | Yes |  | Enforce Unit |
| 1.5 | **APTT/APTR** | LBTEST  LBORRES  LBORRESU | Real  99.9 | seconds | 1 | No | yes |  |  |
| 1.6 | **PT** | LBTEST  LBORRES  LBORREU | Real  99 | Seconds | 1 | No | Yes |  |  |
| 1.7 | *or* **INR** | LBTEST  LBORRES  LBORRESU | Real  99.9 | Seconds | 2 | No | yes |  |  |
| 1.8 | **ALT/SGPT** | LBTEST  LBORRES  LBORRESU | Real  9999.9 | U/L | 1 | No | Yes |  |  |
| 1.9 | **Total Bilirubin** | LBTEST  LBORRES  LBORRESU | Real  99  Category | µmol/L *or*mg/dL | 1 | no | yes |  | Enforce Unit |
| 1.10 | **C-reactive protein** | LBTEST  LBORRES  LBORRESU | Real  999.9  Category | mg/L *or* nmol/L | 1 | No | Yes |  | Enforce Unit |
| 1.11 | **AST/SGOT** | LBTEST  LBORRES  LBORRESU | Real  9999.9 | U/L | 1 | No | yes |  |  |
| 1.12 | **Glucose** | LBTEST  LBORRES  LBORRESU | Real  999.9  Category | mmol/L *or* mg/dL | 1 | No | Yes |  | Enforce Unit |
| 1.13 | **Erythrocyte Sed Rate** | LBTEST  LBORRES  LBORRESU | Real  9.99 | mm/h | 1 | No | yes |  |  |
| 1.14 | **Blood Urea Nitrogen (urea** | LBTEST  LBORRES  LBORRESU | Real  999.9  Category | mmol/L *or*mg/d | 1 | No | Yes |  | Enforce Unit |
| 1.15 | **Lactate** | LBTEST  LBORRES  LBORRESU | Real  99.9  Category | mmol/L *or* mg/dL | 1 | No | yes |  | Enforce Unit |
| 1.16 | **LDH** | LBTEST  LBORRES  LBORRESU | Real  999 | U/L | 1 | No | Yes |  |  |
| 1.17 | **Creatine kinase CPK** | LBTEST  LBORRES  LBORRESU | Real  999.9 | U/L | 1 | No | yes |  |  |
| 1.18 | **Creatinine** | LBTEST  LBORRES  LBORRESU | Real  9999.9  Category | mol/L *or* mg/dL | 1 | No | Yes |  | Enforce Unit |
| **Module 3. CHEST X-RAY** | | | | | | | | | |
| 2.0 | **Are results available for a chest x-ray performed on *the date in section 1 above?*** | REPERF | Category | Yes/No |  |  |  |  | WARN If REPERF = Yes  MSG – Chest X-ray must have been performed on the same date given for Q1. Date of Assessment |
| 2.1 | **Are infiltrates present?** | RETEST  REORRES | Category | Yes/No/N/A |  | YES |  |  | Collect IF REPERFF= Yes and enforce no null allowed |
| 2.2 | **If YES:** Check all quadrants where infiltrates are present: | RELOC | Category | Right upper/Right lower/Left Upper/Left Lower/N/A |  | YES |  |  | Collect IF REPERFF= Yes and enforce no null allowed |

**PATHOGEN TESTING**

| **Question #** | **Question Text** | **CDASH Variable Name** | **Type** | **Value** | **Level** | **Blinded** | **Null allowed** | **Range Check** | **Notes** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Module 4 –PATHOGEN TESTING:** Results of pathogen testing done during this illness episode What about name of testing lab. If the patient is transferred from another centre | | | | | | | | | |
| 1.0 | 🞎YES *(complete section)* 🞎NO 🞎N/A | LBPERF | Category | Yes/No/N/A | 0 |  | NO |  |  |
| 1.1 | Collection Date | LBDAT | Date time | DD/MM/YYYY | 1 |  |  |  |  |
| 1.2 | Bio specimen Type | LBSPEC | Category  Free text | Nasal/NP swab/ Throat swab/ Combined nasal and throat swab/Sputum/BAL/ETA/Urine/Faeces/rectal swab/Blood  IF yes to other: | 1 |  |  |  |  |
| 1.3 | Laboratory Test Method | LBMETH | Category  Free text | PCR/Culture/Other  IF yes to other: | 1 |  |  |  |  |
| 1.4 | Result | LBORRES | Category | Positive/Negative/N/A | 1 |  |  |  |  |
| 1.5 | Pathogen Tested/Detected | LBPATH | Free text |  | 1 |  |  |  |  |

**MEDICATION**

| **Question #** | **Question Text** | **CDASH Variable Name** | **Type** | **Value** | **Level** | **Blinded** | **Null allowed** | **Range Check** | **Notes** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Module 5 – MEDICATION: ANTI-INFECTIVES & CORTICOSTEROIDS** *– List all anti-infectives and corticosteroids administered during hospitalisation and at discharge. Use as many pages as required.* | | | | | | | | | |
| 1.0 | Name of medication *(generic name preferred)* | CMTRT | Category |  | 1 |  |  |  |  |
| 1.1 | **Dose and frequency**  *(specify or unknown* | CMDOSE  CMDOSU  CMSDOSFRQ | Free text  Category  Free text  Category | Days or Weeks | 1 |  |  |  | Enforce Unit |
| 1.2 | **Start date** *(DD/MM/20YY)* | CMSTDAT | Date/Time DD/MM/YYYY |  | 1 |  |  |  | WARN and REJECT IF CMSTDAT < HOSTDAT  MSG – This date is before admission date to facility |
| 1.3 | **End date**  *(DD/MM/20YY)* | CMENDAT | Date/Time DD/MM/YYYY, check box (on-going) |  | 1 |  |  |  |  |
| 1.4 | **Route of administration** | CMROUTE | Category  Free text | IV/Oral/Inhaled/N/A/  Other  IF yes to Other: | 1 |  |  |  |  |