NEW STUDY DOCUMENTS AND SOPs

1. Data Access and Sharing Policy

As specified in article 3.3 of the Data Transfer Agreement: "Parties shall make further separate arrangements in writing regarding the governance, access and use of the data by other parties and publications." These further separate agreements have been described in a Data Access and Sharing Policy attached. In this document ethical principles, governance procedures, a practical guideline for data access and publication are described. **We ask the Local Principal Investigator to inform us on their agreement with this document within 7 days.**

2. Updated Case Report Form

Based upon the first experience and feedback from participating centres (thank you!) we have made some changes to the CRF of CAPACITY. Furthermore, ISARIC-WHO has released a new CRF (version 24APR20) which has been incorporated into the CAPACITY REDCap project. The most important changes to the CRF are delineated below. **Note: One of these changes requires a question to be answered again (in red).** If you have any questions or remarks regarding the updated CRF's please let us know. A document with the most frequent asked questions (FAQ) can be downloaded from our website.

2.1. Summary of changes CAPACITY CRF

a. A date of diagnosis was added per subtype of arrhythmia in the following data collection instruments:

   - CAPACITY – Cardiac Baseline Assessment
   - CAPACITY – Cardiac COVID-19 complications

b. For outcome analyses, the cause of death has been further specified (we specifically ask centres to go back to the discharge form and re-specify the cause of death for every patient):

   - Cardiac causes:
     o Myocarditis
     o Pericarditis
     o Endocarditis
     o Heart failure
     o Cardiac ischemia
     o Arrhythmia
     o Other
   - Pulmonary causes:
     o Pulmonary embolism
     o Other
   - Other (specify in free text)

2.2. Summary of changes ISARIC CRF

c. Two new data collection instruments have been created;
- ISARIC – Pre-Admission Medication
- ISARIC – Medication

d. ISARIC/CAPACITY – Inclusion criteria
- Removed
  - Epidemiological factors section

e. ISARIC/CAPACITY – Demographics
- Removed
  - Baby's COVID-19/SARS-Cov2 testing method
  - Breastfeeding discontinuation date
  - Appropriate child development for age (Y/N)

f. ISARIC – Onset and Admission
- Removed
  - Name of transfer facility, admission date at transfer facility, participant ID # at transfer facility
- Changed
  - "Admission date at this facility" changed to "Most recent presentation/admission date at this facility"

g. ISARIC – Signs and Symptoms at Hospital Admission
- Removed
  - Ear pain and skin ulcers
- Added
  - Height and weight
  - Symptoms: loss of taste and smell, anorexia, inability to walk

h. ISARIC – Co-morbidities and Risk Factors
- Co-morbidities: diabetes diagnosis (type I/II), tuberculosis, asplenia, hypertension and whether receiving ART for HIV/aids

i. ISARIC – Daily Form
- Added
  - Methods of non-invasive ventilation (BIPAP, CPAP)
  - Is the patient currently receiving RRT or dialysis
  - LDH, troponin I, D-Dimer, Ferritin, IL-6

j. ISARIC – Treatment
- Removed
  - Free text option for "Other intervention or procedure"

- Added
  - Max O_2 flow volume, Prone positioning
  - Duration (in days) questions for non-invasive ventilation and ECMO

k. ISARIC – Infectious Respiratory Disease Diagnosis
- Changed
  - "Yes – Probable option" removed for all tests, either "Positive", "Negative" or "Not done"
  - CT diagnostics info (was previously in daily laboratory results section)

l. ISARIC – Outcome
- Removed
  - "Dialysis/renal treatment?" and "other intervention or procedure" From "post-discharge treatment"

m. ISARIC – Complications
- Added
  - Pulmonary embolism, myocardial infarction, endocarditis, cardiomyopathy

3. Data quality: Operating Procedure for quality checks by centres

To guarantee the quality of the collected data within REDCap, we have the two following actions: (1) Regular checks will be performed by the datamanagers of CAPACITY. The results of these quality checks will be reported to all participating centres (2) Quality checks have been built in REDCap, which participating centres can perform **themselves**. Please see the "**Operating Procedure for quality checks by centres**" online. We kindly request each centre to complete the following fields for records created thus far, as these forms contain data that are most important for analyses in the main paper:

- ISARIC/CAPACITY - Participant Identification Number Pin
- ISARIC/CAPACITY - Inclusion Criteria
- ISARIC/CAPACITY – Demographics
- CAPACITY - Cardiac baseline assessment
- CAPACITY - Cardiac COVID-19 complications
- CAPACITY - Cardiac outcome 7-day follow-up
- CAPACITY - Cardiac outcome 30-day follow-up
- CAPACITY – Discharge

4. Sharing ISARIC data with the University of Oxford

We have received a number questions on how the ISARIC data can be shared with the University of Oxford. For more information please see: "**Operating Procedure sharing Data with ISARIC**" online.