CCP Global; Where to start?

ASSESSING SITE CAPACITY

ISARIC/WHO Clinical Characterisation Protocol for Severe emerging infections: COVID-19

INCLUSION CRITERIA

- Children and adults with suspected or confirmed novel Coronavirus (COVID-19) infection.

DATA COLLECTION (TIER 0 TO TIER 3)

- ISARIC/WHO COVID-19 Case Report Form (paper CRF or web-based electronic "eCRF") to be completed.
- Chose to use the COVID-19 Core CRF, or the RAPID CRF.
- Depending on local resources, interest and feasibility, chose which Tier to use. You can choose to change tier at a later date; The patient data recorded is the same for all tiers.
- We encourage sites to enter data onto the eCRF(s) available in REDCap database, hosted by University of Oxford. Sites retain ownership of the data, but can chose to contribute to combined analysis. This option will generate a dynamic dashboard displaying key data for each site. Alternatively sites can set up independent databases (R-code supplied).

TIER 0

- Patient data (CRF)

SAMPLING (TIER 1 TO TIER 3)

- We encourage sites to take part in either, (i) Basic Sampling on enrolment, or (ii) Serial Sampling, if resources allow.
- Read the Clinical Characterisation Protocol to make an assessment to decide if you have the resources and capacity to do: Sampling on Enrolment (Tier 1) and/or Serial Sampling (Tier 2 or 3).

Tier 1: Patient data (CRF) Single Biological Sample

Tier 2: Patient data (CRF) Serial Biological Sampling

Tier 3: Patient data (CRF) Population Pharmacokinetics of antimicrobials & immune modulators

Core resources*

- Access to study participants
- Staff resources to complete CRF
- Internet Access
- Printer, if using paper CRF
- Computer or electronic device/tablet if entering data onto the eCRF in REDCap.

* Note: Check with your local ethics/IRB if they require approval for patient data.

Core resources

- Local ethics and other approvals, as required
- Access to study participants
- Staff familiar in taking informed consent
- Staff resources to complete the data fields in the COVID-19 CRF
- Internet access
- Printer, if using the paper CRF
- Computer or electronic device/tablet if entering data onto the eCRF in REDCap
- Sampling consumables (venepuncture sets, blood tubes, swabs etc.)
- Laboratory capacity to do the laboratory analyses depending on the Tier chosen
- Staff familiar in handling and labelling research samples
- Diagnostic tests and reagents required for analysing the samples
- Facilities for processing samples e.g. biological safety cabinet, centrifuge etc.
- -80 degrees centigrade freezer for storing multiple samples

Where to start, Version 2, 20th May 2020 [Based on the WHO/ISARIC Clinical Characterisation Protocol (CCP), Version 3.1/3.2; Citation: Dunning, J. W., et al. (2014). "Open source clinical science for emerging infections." Lancet Infect Dis 14(1): 8-9].