

FREQUENTLY ASKED QUESTION'S (FAQ) REDCap CRF

GENERAL INFORMATION:

CAPACITY is an international patient registry launched by the University Medical Centre Utrecht in the Netherlands at the beginning of the COVID-19 pandemic. This patient registry was specifically established to determine the role of cardiovascular disease in patients with COVID-19. In the United Kingdom, University College London Hospitals has been assigned as the coordinating centre.

The case report form (CRF) within CAPACITY was based on the CRF released by ISARIC (International Severe Acute Respiratory and Emerging Infection Consortium) in response to the COVID-19 outbreak, and extended with additional data collection instruments to collect in-depth information regarding cardiovascular history, the use of cardiovascular medication, additional cardiovascular examinations and - outcomes. Within **CAPACITY** data generated in the context of routine clinical care is collected in a standardized manner. Patients do not undergo any additional investigations.

Since the entire core CRF of ISARIC (version 24APR20) has been incorporated into the CAPACITY REDCap project, it is also possible to collect ISARIC data within CAPACITY. The only deviation from the 24APR20 ISARIC CRF is the '*Infectious Respiratory Disease Pathogen Testing*' form. In the original instrument as released by ISARIC, the test results are entered as free text. We expected that this would cause difficulties later on during analyses of the data. For this reason, we changed the free text fields into dropdown menu's containing the most likely pathogens (based on the CRF of the REMAP-CAP trial).

For centres that wish to participate in both ISARIC and CAPACITY, it is possible to collect all information in the CAPACITY REDCap project. The data collected specifically for ISARIC can easily be exported and shared with the ISARIC team at the University of Oxford. For further information, please consult the instruction "Sharing ISARIC data with the University of Oxford"

For more information regarding CAPACITY: www.capacity-covid.eu

For more information regarding ISARIC: <https://isaric.tghn.org/>

FREQUENTLY ASKED QUESTION'S (FAQ)

GENERAL QUESTIONS:

What is the best way to inform patients about the registration?

Currently in the UK data is being processed under the Control of Patient Information Regulations Notice. We refer to the UCLH COVID-19 Response Privacy Notice at <https://www.uclh.nhs.uk/aboutus/Pages/Cookiepolicy.aspx> where CAPACITY is explicitly discussed. The Notice is due to expire on 30th September 2020 and CAPACITY UK Is preparing to seek support from the Confidentiality Advisory Group in England which will advise on the best way of advising patients and honouring Opt Outs, should they support exemption under Section 251 of the NHS Act 2006. CAPACITY is in discussions with the equivalent Scottish and Northern Irish Privacy Panels with regards the Duty of Confidence and engagement with patients. We will update these points shortly.

What is the difference between saving something in REDCap as “incomplete” and “unverified”?

“Incomplete”: the data collection instrument has not yet been completely filled out.

“Unverified”: the research professional has doubts about certain data points that have been filled in and for example wants a physician to have a look at it. When all data points have been filled in completely, the data collection instrument can be saved as “complete”. Do not save incomplete data collection instruments as “complete”.

How do I fill in that a patient has been transferred from another hospital?

At the moment, it is difficult to determine the previous study ID of a patient if a patient is transferred from another hospital. If possible, indicate which centre the patient has been transferred from. At a later stage the study IDs will be matched based on the NHS number to filter out double patient entries.

How can I add multiple ECGs in REDCap?

Click the “+ add new” button in ‘Record Home Page’ at ‘Days CAPACITY and ISARIC’. This allows you to create repeating instruments. The same applies to biomarkers, echocardiography and all other data collection instruments within this group.



How to handle a re-admission of a patient?

We would like to have one record per patient and have the follow-up period as long as possible. In case of re-admission due to COVID-19, the baseline data collection instruments remain unchanged. However, in the ‘repeating instruments’ new relevant information can be added (see figure below). Please register all complications that occurred during the entire period a patient was admitted to a hospital in the ‘*Cardiac COVID-19 complications*’ form. Furthermore, if needed change the 7- and 30-day follow-up forms (count the days from the first admission day of the first admission) and adjust the information collected in the ‘*Discharge*’ form to match with the last admission.

Days CAPACITY and ISARIC						
ISARIC - Daily Form (OPTIONAL)	CAPACITY - Cardiac biomarkers (OPTIONAL)	CAPACITY - ECG (OPTIONAL)	CAPACITY - Echocardiography (OPTIONAL)	CAPACITY - Cardiac MRI (OPTIONAL)	CAPACITY - CT (thorax/coronaries/PET/lung angiography) (OPTIONAL)	CAPACITY - Invasive Cardiac Procedures (OPTIONAL)

Date of proven COVID-19: what to fill in?

The day that the test was performed.

Since a pulmonary embolism is not a cardiac complication, why is this complication recorded?

Pulmonary embolisms appear to occur frequently in patients with COVID-19 and are often treated by the Department of Cardiology elsewhere in Europe.

QUESTIONS: CAPACITY – 7 and 30-day follow-up

What to fill in at the 7-day and 30-day follow-up forms, 7 and 30 days after the diagnosis of COVID-19 or 7 and 30 days after the first admission?

Start counting from the first day of the first hospital admission.

QUESTIONS: CAPACITY – Discharge

If a patient is discharged to a nursing home, should you choose ‘transfer to other facility’ of ‘discharged alive’ as an outcome at the Discharge data collection instrument?

Choose the option “Discharged alive”. “Transfer to other facility” only applies for transfers to other hospitals.

Why do you have to fill out the COVID-19 infection status twice (at baseline and at discharge)?

At baseline, not every patient may have been tested positive for SARS-CoV-2 despite a high suspicion of disease (limited test sensitivity). To make sure that we can distinguish the patients that (1) were highly suspicious of having COVID-19 but have never had a positive PCR and (2) patients that were tested positive, this question is asked again at discharge.