FREQUENTLY ASKED QUESTIONS

EUROPEAN SOCIETY OF INTENSIVE CARE MEDICINE COVID-19 Project (UNITE-COVID)

Last updated 14 September 2020

	Question	Response
Q1	Who can I contact if I have any questions?	Guy FRANCOIS (guy.francois@esicm.org) or the Principal Investigators: Pr Dr. Jan DE WAELE (Jan.DeWaele@UGent.be)
Q2	Who is my National Coordinator (NC)?	You can find this information and all of the UNITE-COVID documents at https://www.esicm.org/research/trials/trials-group-2/unite-covid/
Q3	Is there any financial support for research ethics board fees or my research personnel?	No, there is no financial compensation for participation. Participation in the study is completely voluntary.
Q4	Can I register more than 1 ICU in my centre?	Absolutely! Please register any general (medical and surgical) or specialist ICU (e.g., neuro ICU, cardiovascular ICU) at your centre that provides care for ADULT patients. One person may serve as the local investigator for all sites, or there may be a different investigator for each ICU.
Q5	Do I need IRB (Institutional Review Board) approval?	As this is a retrospective observational study, and not an interventional study, ethics committee approval may or may not be required depending on which country your ICU is located. You must check with your local ethical committee as to whether approval is required. IRB approval must be obtained for each center if required by its local regulations. In some countries, a National coordinator can be of help to obtain IRB approval.
Q6	Can I start enrolling patients before I have IRB approval?	Centres should NOT enrol any patients prior to receiving ethics approval if this is required by your local ethical regulations. It is the local investigator's responsibility to ensure that local approvals are in place at their centre prior to the initiation of the study.
Q7	Does this study require informed consent?	This is an observational study, and for it to yield useful information, we must be able to include all patients in ICU on the day between Feb 15th and June 15th, 2020 with the highest number of COVID-19 patients in your unit or in any other place of the hospital under the care of the critical care team, if they fulfil the criteria. Requiring patient informed consent makes this very difficult. Ethics committees are generally aware of this issue, and will frequently waive consent for an observational study such as this.

Q8	there isn't any mention of consent in the protocol – am I correct in understanding that consent is not required?	Since this is a purely observational retrospective study, in most countries, national or local ethical committees may waive the need for informed consent. However, please check with your national coordinator or local ethical committee if you are not sure.
Q9	When can I start enrolling patients?	You can enrol patients after you obtained the ethical/IRB approval if needed and after you will have received your credentials to access the eCRF platform from us.
Q10	Are paper Case Report Forms (CRF) available for data entry?	We provide centres with a paper CRF but require them to enter data in the electronic CRF as well.
Q11	Can I enrol as many patients as possible?	Yes, provided that that they were present in the ICU or under ICU-team care on the day you selected and of course provided that they fulfil the inclusion criteria
Q12	How long do I collect data for each patient?	For each patient, ICU data will be collected until 60-day follow-up.
Q13	Can I participate if I work in a paediatric or neonatal ICU?	Unfortunately not. UNITE-COVID includes patients aged 18 years and over only.
Q14	When can I have access to the eCRF?	*To be communicated to registered centres at a later stage.*
Q15	Can I apply to be National Coordinator (NC) in my country?	National coordinators will be appointed by the steering committee. If you have a question, please contact Guy FRANCOIS (guy.francois@esicm.org)
Q16	As an Investigator, will I be listed as contributor in the final report/paper?	Any center that has obtained ethics committee approval (if necessary according to local regulations) and that included at least 2 patients can have 1 collaborator mentioned in the list of collaborators attached to the publication of the primary paper. In case more cases are included the following applies: 20 or more patients: 2 collaborators; 50 or more patients: 3 collaborators; 100 or more patients: 4 collaborators.
Q17	Can I have a proof of participation in the study for my CV?	Yes. We would be happy to provide a letter for National Coordinators or Investigators who have included patients in this study. Please contact Guy FRANCOIS (guy.françois@esicm.org)
Q18	Is the eCRF platform GDPR compliant?	Yes. You can find this information and all of the UNITE-COVID documents at https://www.esicm.org/research/trials/trials-group-2/unite-covid/
Q19	Does the eCRF exist in other languages?	No.
Q20	Can I publish my own center data?	After the primary UNITE-COVID manuscript is published, site investigators may publish their own site's data which was collected locally.
Q21	If discharged alive/transfer, hospital admission duration (days): Do you mean ward stay or total hospital stay?	it is the total hospital stay and therefore it will include ICU stay as well.
Q22	In the domain respiratory: prone session	we decided to register the number of sessions the patient had (equivalent to 16hours per day). Is it correct? A:nswer: 16h in a day would be 1 day indeed
Q23	In the domain respiratory: weaning process	for the weaning process classification (normal, difficult and prolonged) we used the literature classification of European Respiratory Journal (Doi: 10.1183/09031936.00010206). Is it correct?

		Answer: Yes
Q24	In the respiratory domain, the CRF asks if the patient received HFNC/CPAP/NIV during the ICU stay. Where it asks for the answer, it says to input number of days they were used before intubation, which is different to the initial question. The patient I'm currently looking at received CPAP after extubation, but during ICU stay. Should I say he received it or not? If I say he did, I need to say how many days he received it before intubation. But the question is if he received it during ICU stay, not before intubation.	- If the patient received HFNC, CPAP or NIV – click on yes. o If it was only before intubation, enter the number of days before (that would be the number of calendar days the patient was on NIV – could be intermittent as well during the day) o If it was before and after, enter the number of the days before intubation o if it only was after intubation then enter 0
Q25	**Ventilatory settings the first day of mechanical ventilation.** They could vary a lot during the day. What value is requested? the first value recorded, or a certain time after the intubation, or the worst one during the day?	If multiiple settings are used then the setting that was used during most of the interval eg if a patient was on SIMV for 2 hours and BIPAP 22 h, please enter BIPAP