EUROPEAN SOCIETY OF INTENSIVE CARE MEDICINE COVID-19

FREQUENTLY ASKED QUESTIONS

(UNITE-COVID)

Last updated 14 May 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 in April 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	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.
Q9	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.
Q10	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
Q11	How long do I collect data for each patient?	For each patient, ICU data will be collected until 30-day follow-up.
Q12	Can I participate if I work in a paediatric or neonatal ICU?	Unfortunately not. UNITE-COVID includes patients aged 18 years and over only.
Q13	When can I have access to the eCRF?	*To be communicated to registered centres at a later stage.*

Q14	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)
Q15	As an Investigator, will I be listed as contributor in the final report/paper?	All site investigators who recruit a minimum of 10 patients will be listed as collaborators. For further information please refer to the UNITE-COVID webpage and protocol
Q16	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)
Q17	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/
Q18	Does the eCRF exist in other languages?	No.
Q19	Can I publish my own center's data?	After the primary UNITE-COVID manuscript is published, site investigators may publish their own site's data which was collected locally.