FAQ - ENCORE study

1. Should I include this patient?

Please follow Inclusion/exclusion criteria in eCRF. Essentially, all patients in Stages I-III (not Stage IV-distant metastases M1) are included. All colorectal cancers are included (right, left or transverse colan and of course rectal. If precise staging is unclear before surgery start, include patient in paper CRF and enter to eCRF once diagnosis confirmed (Stage I-III). If a patient seems eligible preoperatively, but then in the operating room surgeons discuover a metastasis or something different that changes the preoperative stage, patient must be excluded. Patients must NOT be included into the study if the surgery is due to a local or regional **recurrence** of cancer AFTER index surgery. For instance, patient was not included in ENCORE for index surgery but returns for surgery due to recurrance from local or regional spread of cancer. This patient **will NOT be included** into the study.

Patient with Neuroendocrine tumor (NET) **are excluded** from the study.

Patients with the following two surgical techniques **should not be included**

- Transanal Minimal Invasive Surgery (TAMIS)
- Transanal Endoscopic Microsurgery (TEM)

Some patients with cancer of the rectum get both neoadjuvant chemotherapy and radiation. Many of these patients get a stoma operation before treatment to prevent complications regarding stenosis. This is not tumour surgery. According to the criteria, these can be included.

2. When should I fill in the eCRF?

We recommend that you start by filling in paper CRF first and later (e.g. after 30 - 90 days when data is complete) you could essentially open eCRF and copy-paste from paper CRF. This saves time and opening-re-opening the eCRF.

3. Should I save the paper CRF for all patients?

We recommend that you save all paper CRF for later reference in case of doubts and uncertainties. This may also be useful when ESAIC is doing data cleaning at the end of the study when sometimes false data/uncertain data may have been entered into eCRF.

4. Should I enter data completed after 90 days?

Yes. Please enter all data up to 90 days when we expect that patients who need adjuvant chemotherapy have received it, which is one of two primary endpoints. In this way we will be able to start analysing the first part of the study as soon as we have reached the necessary number of patients. Please enter data for ALL patients (all three cancer stages) at 90 days, not just those that receive chemotherapy.

5. It is difficult for the Anesthesiologist to enter surgical and oncological data.

What should we do?

Ideally, it is important to have a surgeon on the team from each hospital. This will ensure that correct data is entered in the CRF. If this is not possible, we will encourage each hospital to have a dialogue

with the surgeon before the 90 day period (and ideally a continuous dialogue) so the relevant data is correctly entered.

6. We don't have the data requested in CRF. What should we do?

If data is missing, for different reasons, please enter "not known" or leave it empty unless it is an obligatory field marked by an *. We will naturally encourage all investigators to enter full data on each patient but it is better to have no data than incorrect data!

7. Patient was staged III at diagnosis but later confirmed to be Stage IV. What do I do?

This patient has to be excluded (not entered in eCRF). If you have a paper CRF, please keep a copy for future reference, even though the patient was excluded from ENCORE.

8. I am not sure how to enter some data into eCRF. How do I proceed.

Please refer to the eCRF completion manual. The National Coordinator (NC) is the person who has the most information about the study. If your own primary investigator (PI) at your hospital cannot answer a question, check first with the NC (list of NCs and their emails are available on the home page). If the NC cannot answer the question, they will get in touch with ESAIC who may answer the question (if its technical problem) or refer to Steering Committee (SC) if it is a medical issue.

9. What happens if the PI moves to another hospital or is not involved in ENCORE?

Ideally, the PI should report to ESAIC that he/she has moved to another hospital and will not take further responsibility for ENCORE, preferably with an alternative name at the hospital who will continue to take responsibility. If the PI is inactive (in your opinion), please correspond either with the NC or ESAIC directly so will will try to help sort out the issue professionally.

10. Who does the follow-up of patients after they return home?

The best way is to follow up the patient personally, as PI (or via the doctor/nurse that took care of the patient during their stay in the hospital), but this may no always be possible. Medical records can be checked to see re-visits to the hospital or follow-up by surgeons and oncologists. Sometimes the patient knows the most and one can call the patient at home and discuss the relevant part of the questionnaire. It is then a good idea to enter the information obtained into the medical record since you may be the only person who knows these facts. Additionally, in case of further monitoring of your site (hospital) we can confirm the correctness of the data through your entry into medical records. If you are unable to get the necessary information, please enter "lost to follow-up". This should be exceptional, not routine.