European Society of Anaesthesiology and Intensive Care

ENCORE Patient Identification Coversheet for CRF

Confidential

This coversheet is intended to help site staff link local patient data to the study-specific patient identification code.

After completing follow-up, this coversheet should be saved separately from the CRF and filed in a secure place. The information on this coversheet will NOT be collected in the CRF.

This coversheet is for local use ONLY.

Patient Identifying Data	
Date paper CRF created	|__|__| / |__|__|__| / |__|__|__|__| (dd/Mmm/YYYY)
Subject Date of birth	|__|__| / |__|__|__| / |__|__|__|__| (dd/Mmm/YYYY)
Subject ID (OpenClinica eCRF Subject ID number)	|__|__|__|-|__|__|__|-|__|__|__| (Use the 3 digit code for the country, 3 digit code for the hospital and 3 digit individual patient number)
Identification *Complete with available data*	Patient Hospital/local Identification Number (handwritten or sticker): First name: Last name:

Please cross the boxes below when data has been entered.

CRF number	Paper CRF	OpenClinica electronic CRF
CRF1: Data		
Section 1: Preoperative variables	☐	☐
Section 2: Preoperative staging and Management	☐	☐
Section 3: Surgical and Operative Characteristics	☐	☐
Section 4: Anaesthesia and Analgesia (Intraoperative)	☐	☐
Section 5: Postoperative Management until home discharge	☐	☐
CRF2: Follow-up at 90 days	☐	☐
CRF3: Follow-up at 3 years	☐	☐

European Society of Anaesthesiology and Intensive Care

ENCORE: Case Report Form

Effects of Anaesthetics on colorectal cancer outcomes

CRF1: Operative Data

Section 1: Preoperative variables

1. Subject ID*	|__|__|__|-|__||__||__|-|__||__||__| *Use a 3 digit code for the Country, Hospital and individual Patient number, respectively, separated with hyphens: xxx-xxx-xxx*		
2. Written informed consent applicable?*	○ No ○ yes	If yes, date of written informed consent |__|__|-|__||__|__|-|__||__|| *(dd-Mmm-YYYY)*	
3. Age (years)*	|__|__|__| [18-100]	4. Sex	○ M ○ F
5. Weight (Kg)*	|__|__|__| [30-180]	6. Height (cm)	|__|__|__| [120-210]
7. Regular tobacco consumption*	○ Never ○ Stopped > 30 days ○ Stopped < 30 days ○ Current ○ Not available		
8. Regular alcohol consumption*	○ No ○ Yes: < 5 standard glasses / week ○ Yes: 5-10 standard glasses / week ○ Yes: >10 standard glasses / week ○ Not available		

Co-morbid conditions (preoperative)

9 Previous stroke or TIA (Transient ischemic attack) *	○ No	○ Yes
10 Hypertension*	○ No	○ Yes
11 Angina pectoris*	○ No	○ Yes
12 Cardiac failure*	○ No	○ Yes NYHA I ○ Yes NYHA II ○ Yes NYHA III
13 COPD (Chronic obstructive pulmonary disease)*	○ No	○ Yes
14 Diabetes mellitus*	○ No	○ Yes, Type I ○ Yes, Type II on oral medications ○ Yes, Type II on oral medication and/or insulin
15 Liver disease*	○ No	○ Yes, Childs-Pugh A ○ Yes, Childs-Pugh B/C
16 Renal insufficiency*	○ No	○ Elevated creatinine (> 110µmol/L for males, >100 µmol/L for females OR eGFR < 60 mL/min/1.73m^2) ○ Peritoneal dialysis ○ Hemodialysis
17 Other cancers*	○ No	○ Yes. If yes, please enter details below:

17.1 Type of cancer	* 17.2 Status
	○ Resolved (no further follow up) ○ Not resolved (ongoing)
	○ Resolved (no further follow up) ○ Not resolved (ongoing)
	○ Resolved (no further follow up) ○ Not resolved (ongoing)

18 Family History of Colorectal Cancer*		○ No	○ Yes, immediate relative ○ Yes, distant relative (cousins, uncles/aunts) ○ Not available
Preoperative chronic medication (>1 month preoperatively)			
19 Statins*	○ No	○ Yes	
20 Beta-Blockers*	○ No	○ Yes	If yes, Name:
21 Angiotensin-converting enzyme inhibitors (ACEi)/Angiotensin II Receptor Blockers (ARB) *	○ No	○ Yes	
22 Aceytylsalycilic acid (Aspirin)*	○ No	○ Yes	
23 Opiate analgesics*	○ No	○ Yes	
24 Non-steroidal anti-inflammatory drug (NSAID) *	○ No	○ Yes	If yes, Name:
Physical Functioning Status			
25 ASA-Physical status*: *(see Appendix 11: ASA Physical Status Classification* *ENCORE Appendix 11: ASA-Physical status Classification | ESAIC)*	○ ASA 1: Healthy person ○ ASA 2: Mild systemic disease ○ ASA 3: Severe systemic disease ○ ASA 4: Life threatening disease		
26. mDASI-q4 (Modified Duke Activity Status Index)*. Mark maximum (best) capacity *(see Appendix 12: mDASI 4q* *ENCORE Appendix 12: mDASI - 4q | ESAIC)*	○ Bed-ridden or only minimal work at home ○ Able to climb a flight of stairs or walk up a hill ○ Able to do heavy work around the house (lifting and moving heavy furniture) ○ Able to do yard work (raking leaves or pushing a mower) ○ Able to participate in strenuous sports (swimming, tennis, football, skiing)		
27. Nutritional State*	○ Normal nutrition, no weight loss in last 3 months ○ >5% weight loss in last 3 months ○ Poor intake in past week ○ Weight loss status not known		
28. Was patient referred to Prehabilitation program*	○ No ○ Yes. 28.1 If yes, for how long: ○ <2 weeks ○2-4 weeks ○ >4 weeks duration		
	28.2* If yes, choose program(s) attended: ☐ Smoking cessation > 4 weeks before surgery ☐ Supervised aerobic exercise training before surgery (walking, cycling etc.) ☐ *Supervised* resistance training e.g. gymnastic exercises ☐ Breathing exercises ☐ Nutritional program ☐ Anemia optimization with iron infusion ☐ Psychology support ☐ Education class – (ERAS, Surgery School) ☐ Other		

Lab tests (within 30 days of **surgery**) : If several, select test done closest to time of surgery

	Result *(Write NA if not available.)*	Unit *(Please select appropriate unit)*
29. Albumin*		○ g/dL [1-10] ○ g/L[10-100]
30. Haemoglobin*		○ g/dL [5-20] ○ g/L[50-200 ○ mmol/L[3-15]
31. Total white blood cell (WBC) count*		WBCs/microL [4500-11.000]

32. C-Reactive Protein (CRP) *		mg/L [0 – 500]
33. Creatinine*		○ mg/dL [0.1-10.0] ○ µmol/L [30-1000]
34. Carcinoembryonic antigen (CEA) Level*		ng/mL [0-500]

Section 2: Preoperative staging and Management

35. Position of primary tumor*	○ Appendix	○ Caecum	○ Right colon	○ Transverse colon	○ Left colon	○ Rectum
	35. 1* If, rectum: distance from anal verge measured by rigid rectoscopy ○ low (< 5 cm) ○ mid (5 - 10 cm) ○ high (10 up to 15 cm)					
36. T-Stage Clinical TNM (Primary Tumour) * *(See Appendix 8: Staging of colorectal-cancer ENCORE Appendix 8: Staging of colorectal cancer | ESAIC*	○ T1	○ T2	○ T3	○ T4		
37. Nodes Clinical TNM (Nodes) *	○ N negative		○ N positive			
38. Metastasis Clinical TNM (Metastasis) *	○ M0					
39. PRE-operative (Neo-adjuvant) Chemo-radiotherapy*	○ No	○ Yes. If yes, ☐ 39.1 Chemotherapy: ○ FLOX ○ FOLFOX ○ FOLFIRINOX ○ Other 39.1.1 Date of start of chemotherapy *dd-Mmm-YYYY* |__|__|-|__|__|__|-|__|__|__|__| 39.1.2 Date of end of chemotherapy *dd-Mmm-YYYY* |__|__|-|__|__|__|-|__|__|__|__| ☐39.2 Radiotherapy: 39.2.1 Date of start of radiotherapy *dd-Mmm-YYYY* |__|__|-|__|___|- |__|__|__|__| 39.2.2 Date of end of radiotherapy *dd-Mmm-YYYY* |__|__|-|__|__|__|-|__|__|__|__| 39.2.3 Total Dose: Gy				

Section 3: Surgical and Operative Characteristics

Surgery							
40. Date of Index (primary) surgery*	|__|__|-|__|__|__|-|__|__|__|__| *(dd-Mmm-YYYY)*						
41. Technique*	○ Laparoscopic ○ Robotic ○ Conversion from laparoscopic/robotic to open ○ Open						
42. Resected bowel segment*	☐ Appendectomy ☐ Ileocecal resection ☐ Right-sided colectomy ☐ Extended right-sided colectomy ☐ Transverse colectomy ☐ Left-sided colectomy ☐ Sigmoid resection ☐ (Sub-) total colectomy ☐ Partial mesorectal excision (PME, High Anterior Resection) ☐ Total mesorectal excision (TME, Low Anterior Resection) ☐ Intersphincteric abdominoperineal excision (APE) ☐ Extralevator abdominoperineal excision (APE) ☐ Proctocolectomy ☐ Local excision ☐ None ☐ Other						
43. Resection of additional structures/ organs apart from bowel segment* (e.g. small bowel, urinary tract, genital organs, extra-mesenteric lymph nodes, pelvic sidewall)	○ No ○ Yes						
44. Reconstruction*	○ Primary anastomosis ○ Primary anastomosis with defunctioning stoma ○ Permanent stoma						
45. Duration of the surgery*	|__|__|__|__| 30 – 1200 min						
46. Intraoperative blood loss*	|__|__|__|__| 0 – 9999 ml						
47. Did the patient have a blood transfusion*	○ No ○ Yes If yes, please enter details below:						
	47.1 ERC (red cells)	*|__|__|__|__| (ml)					
	47.2 Plasma (FFP)	*|__|__|__|__| (ml)					
	47.3 Thrombocyte (platelets)	*|__|__|__|__| (ml)					
	47.4 Antifibrinolytics (e.g. Tranexamic Acid used)	○ No ○ Yes					
	47.5 Albumin (ml)	|*__|__|__|__| (ml)					
Histo-pathological Report							
48. T-Stage (Pathological TNM) *	○ T0	○ T1	○ T2	○ T3	○ T4a	○ T4b	○T4a/b

49. Nodes (Pathological TNM)*	49.1. Number of examined regional nodes		[0-99]
	49.2. Number of regional nodes with metastasis?		[0-99]
	49.3. Tumor deposits		○ No ○ Yes
50. Metastasis (Pathological TNM)*	○ M0		
51. R-Category*	○ R0: Resection margin free of microscopic tumor growth	○ R1: Resection margin with microscopic tumor growth	○ R2: Resection margin with macroscopic tumor growth
52. Microscopic circumferential resection margin (CRM)*	○ Presence of tumor cells in resection margin (CRM = 0mm) ○ Tumor cells within 1mm from resection margin (CRM >0 and <1mm) ○ No tumor cells within 1mm from resection margin (CRM 1mm or more)		
53. Extramural vein invasion*	○ No ○ Yes		

SECTION 4: Anaesthesia & Analgesia (Intraoperative)

Anaesthesia		
54. Inhalation anaesthesia*	○ No ○ Yes	54.1 If yes: ☐ Sevoflurane ☐ Desflurane ☐ Isoflurane ☐ N_2O ☐ Other
55. Total Intravenous Anaesthesia (TIVA)-propofol*	○ No ○ Yes	
Analgesia		
56. Neuraxial block*	○ No ○ Yes	56.1 if yes: ☐ Spinal ☐ Thoracic Epidural ☐ Lumbar Epidural ☐ TAPP block ☐ Opiates used with block ☐ Other block used
57. Systemic opiates*	○ No ○ Yes	57.1 If yes: ☐ Fentanyl ☐ Morphine ☐ Remifentanil ☐ Sufentanil ☐ Other
58. Anti-inflammatory adjuncts*	○ No ○ Yes	58.1 If yes: ☐ Steroids (for PONV) ☐ Non-steroidal anti-inflammatory drugs (NSAIDs) ☐ COX-2 inhibitor ☐ Lidocaine infusion ☐ Paracetamol ☐ Metamizole ☐ Others

Section 5: Postoperative Management until home discharge	
59. Were any blood products given* (ERC, Plasma or TRC)	○ No ○ Yes . 59.1 If yes, total volume: ○ < 500 ml ○ 500 - 1000 ml ○ 1000 - 2000 ml ○ > 2000 ml
60. Epidural removed on*	Postoperative Day: ○ 0 ○ 1 ○2 ○3 ○>3 days ○ Not applicable
61. Ineffective epidural requiring intervention*	○ No ○ Yes - New epidural placed postoperatively ○ Yes - Rescued with epidural boluses ○ Yes - Rescue with opioids / PCA ○ Yes - Discontinued earlier than planned ○ Not applicable
62. Total postoperative i.v. morphine equivalents during first 72 hours after surgery*	○ < 10 mg ○ 10 - 50 mg ○ 50 - 100 mg ○ > 100 mg ○ data not available/not possible to convert to morphine
63. Was Non-steroidal anti-inflammatory drug (NSAID) given postoperatively*	○ No ○ Yes
64. Postoperative Noradrenaline or phenylephrine infusions for BP support*	○ No ○ Yes
65. Postoperative destination for 1st night after surgery (PACU if remains in recovery, HDU if transferred to high-dependency but not ICU)*	○ Ward ○ Extended Post Anaesthesia Care Unit (PACU) ○ High Dependency Unit (HDU) ○ Intensive Care Unit

CRF2: Follow-up at 90 days	
Short-term: To be filled in at 90 days (±14 days) from date of index (primary) surgery	
66. If postoperative complications within 30 days, which organ system (tick all that apply)* *(See Appendix 13: Postoperative Complications ENCORE Appendix 13: Postoperative complications | ESAIC)*	☐ No postoperative complications within 30 days ☐ Respiratory ☐ Cardiovascular ☐ Renal ☐ Central nervous system ☐ Infectious ☐ Hematological ☐ Gastrointestinal (including anastomoses) ☐ Other

67. Grade of postoperative complication within 30 days (*list highest Clavien-Dindo grade complication*)*

○ No postoperative complications within 30 days

○ I*: Acceptable therapeutic regimens are: drugs as antiemetics, antipyretics, analgetics, diuretics and electrolytes and physiotherapy. This grade also includes wound infections opened at the bedside.*

○ II*: Requiring pharmacological treatment with drugs other than such allowed for grade I complications. Blood transfusions and total parenteral nutrition are also included.*

○ IIIa*: Requiring surgical, endoscopic or radiological intervention NOT under general anaesthesia*

○ IIIb*: Requiring surgical, endoscopic or radiological intervention under general anaesthesia*

○ IVa*: Single organ dysfunction (including dialysis) requiring IC/ICU-management*

○ IVb*: Multi organ dysfunction (including dialysis) requiring IC/ICU-management*

○ V*: Death within 90 days.* 67.1, Date of death: |__|__|-|__|__|__|-|__|__|__|__| *dd-Mmm-YYYY*

68. Date of discharge from hospital after performing index (primary) surgery*	|__|__|-|__|__|__|-|__|__|__|__| *dd-Mmm-YYYY*
69. Discharge to:*	○ original living facility ○ other care facility ○ unknown
70. Re-admission within 30 days*	○ No ○ Yes
71. Number of days at home (DAH) during 0 - 30 days after index (primary) surgery* (e.g. if 5 postoperative days + 2 days readmission, DAH = 23 days) *Please note that Day 0 = day of surgery. An intervention procedure that is not chemo and does not involve an overnight stay is still counted as a re-admission.*	|__|__|__| days [0-30] ○ Not available

72. POST-operative (Adjuvant) Chemo-radiotherapy*	○ No	○ Yes. If yes, ☐ 72.1 Chemotherapy: ○ FLOX ○ FOLFOX ○ FOLFIRINOX ○ Other 72.1.1 Date of start of chemotherapy *dd-Mmm-YYYY* |__|__|-|__|__|__|-|__|__|__|__| 72.1.2 Date of end of chemotherapy *dd-Mmm-YYYY* |__|__|-|__|__|__|-|__|__|__|__| ☐72.2 Radiotherapy: 72.2.1 Total Dose: Gy

Oncological complications (see protocol for details):

73. New onset Dysesthesia*	○ No ○ Yes ○ Not available	73.1 If yes: Grade ○ I ○ II ○ III
74. New onset Neuralgia*	○ No ○ Yes ○ Not available	74.1 If yes: Grade ○ I ○ II ○ III

75. New onset Paresthesia*	○ No ○ Yes ○ Not available	75.1 If yes: Grade ○ I ○ II ○ III
76.***Worsening*** of oncological side effects compared to before surgery, evaluated when appropriate*	○ No ○ Yes ○ Not available	76.1 If yes: Grade ○ I ○ II ○ III

CRF3: Follow-up at 3 years

Long-term: To be filled in after 3 years (±90 days) from date of index (primary)surgery

77. Was the Carcinoembryonic antigen (CEA) level taken after surgery?*

○ No
○ Yes. If yes please complete table below:

77.1 CEA Date *(dd-Mmm-YYYY)*	77.2 CEA Value ng/ml [0 – 500]
|__|__|-|__|__|__|-|__|__|__|__|	
|__|__|-|__|__|__|-|__|__|__|__|	
|__|__|-|__|__|__|-|__|__|__|__|	
|__|__|-|__|__|__|-|__|__|__|__|	

78. Was the patient followed until first event (death, cancer recurrence) or 3 years postoperatively?*

○ No
○ Yes. 78.1 Date of last follow-up without event:
|__|__|-|__|__|__|-|__|__|__|__| *(dd-Mmm-YYYY)*

79. Death of patient between 90 days and 3 years postoperatively?*

○ No *Please go to questions 79.2 and 79.3*
○ Yes *Please go to question 79.1*

79.1 If Yes: Cause of death related to colorectal cancer resected during index (primary) surgery?*

○ Yes
○ No
○ Not available

79.2 If No: Local recurrence within 3 years postoperatively?*

○ Yes. 79.2.1 If yes, date local recurrence discovered:
|__|__|-|__|__|__|-|__|__|__|__| *(dd-Mmm-YYYY)*

○ No

79.3 If No: Systemic recurrence within 3 years postoperatively?*

○ Yes. 79.3.1 If yes, date systemic recurrence discovered:
|__|__|-|__|__|__|-|__|__|__|__| *(dd-Mmm-YYYY)*

○ No