

# PROCARE study – prospective registration

## Patient data

National number<sup>REQ.</sup>: .....

Name<sup>REQ.</sup>: ..... First name<sup>REQ.</sup>: .....

Date of birth (dd/mm/yyyy)<sup>REQ.</sup>: ...../...../.....

Sex<sup>REQ.</sup>:

- Male
- Female

Zip code of residence<sup>REQ.</sup>: .....

Registration number, provided by the data centre: .....

General practitioner (name, first name): .....

## Hospital data

Contact person (can be a study nurse)

Contact details: Name, first name: .....

Address: .....

Tel. Number: .....

Email address: .....

Name Hospital (1)<sup>REQ.</sup>: .....

Treatment (indicate treatments within the same hospital):

- Surgery: name surgeon(s)**<sup>REQ.</sup> .....
- Preoperative staging
- Radiotherapy
- Chemotherapy
- Pathology report: name pathologist (s): .....
- Follow-up: name responsible physician<sup>REQ.</sup>: .....

Name Hospital (2): .....

Treatment:

- Preoperative staging
- Radiotherapy
- Chemotherapy
- Pathology report: name pathologist (s): .....
- Follow-up: name responsible physician<sup>REQ.</sup>: .....

Name Hospital (3): .....

Treatment:

- Preoperative staging
  - Radiotherapy
  - Chemotherapy
  - Pathology report: name pathologist (s):.....
  - Follow-up: name responsible physician<sup>REQ</sup>: .....
- .....

**OPERATIVE DATA ENTRY FORM**

Registration number, provided by the data centre:.....

Name patient:..... First Name patient:.....

Date of Birth:...../...../.....

**PART I: Pre-treatment data**

**1. Date of first consultation or hospitalisation for rectal cancer<sup>REQ</sup>**

(dd/mm/yyyy): ...../...../.....

**2. Synchronous cancer<sup>REQ</sup> ?**

- no
- yes

**If yes:**

**a) organ(s):**

- breast
- colon
- lung
- gynaecological tumour
- lymphoma
- other, please specify: .....

**b) date of diagnosis: (dd/mm/yyyy):...../...../.....**

**c) cTNM stage: T..... N..... M.....**

**d) pTNM stage: T..... N..... M.....**

**3. Other cancer(s) in patient's past history<sup>REQ</sup>?**

- no
- yes

**If yes:**

**a) organ(s):**

Tumour 1

- breast
- colon
- lung
- gynaecological tumour
- lymphoma
- other, please specify: .....

Tumour 2

- breast
- colon
- lung
- gynaecological tumour
- lymphoma
- other, please specify: .....

**b) actual tumour activity ?**

Tumour 1:

yes

no

Tumour 2:

yes

no

**4. Lower limit primary tumour:.....cm above the margo ani<sup>REQ</sup>**

based on:

- rigid rectoscopy (to be preferred)
- coloscopy (during withdrawal of the coloscopy)

**5. Characteristics of the primary tumour**

**Localisation**<sup>REQ</sup>:

- Ventral
- Lateral right
- Lateral left
- Dorsal

**Upper limit:** .....cm (if possible, in cm above the margo ani)

**Clinical:**

- Mobile
- Fixed
- Not palpable

**6. Pretreatment staging procedures and clinical TNM (UICC 2002)**

Check all staging procedures that were carried out.

**Rx thorax :**  yes  no

**US liver/abdomen:**  yes  no

**CT:**

• Thorax:  yes  no

• Abdomen/pelvis:  yes  no

If yes: cT: .....

cN: .....

cCRM lateral or circumferential margin:.....mm

**MRI:**  yes  no

If yes: cT: .....

cN: .....

cCRM lateral or circumferential margin:.....mm

involvement of the sphincters :  yes  no

**TRUS:**  yes  no

If yes: cT: .....

cN: .....

involvement of the sphincters :  yes  no

**PET:**  yes  no

**PET/CT:**  yes  no

**Other:**  yes  no

If yes, please specify: .....

**cM**<sup>REQ</sup>

- No metastasis
- Metastasis

**If Metastasis:**

**a) Location:**

- Non-mesorectal nodes (including external or common iliac nodes and retroperitoneal nodes above inf. mesenteric artery)
- Liver
- Peritoneum
- Lung
- Bone
- Other, please specify: .....

**b) Based on:**

- Rx thorax
- US liver/abdomen
- CT
- PET
- Other, please specify: .....

**Summary cTNM stage**<sup>REQ</sup>: cT..... N..... M.....

**7. CEA serum before treatment**<sup>REQ</sup>: .....

**8. Colonoscopy**

*Total colonoscopy*<sup>REQ</sup>:

- Yes  
If yes: Simultaneous lesions?
  - No
  - Polyp
  - Carcinoma
  - Other

- No  
If no: Reason?
  - Tumour stenosis
  - Insufficient preparation
  - Intolerance of the patient
  - Technical reasons
  - Other

*Biopsy of the tumour:*

- Yes  
If yes: Date of biopsy<sup>REQ</sup> (dd/mm/yyyy): ..... / ..... / .....  
Result of the biopsy:
  - Adenocarcinoma
  - Other: .....
- No

*Complications:*

- No
- Yes

If yes:

- Oversedation
- Bleeding
- Perforation
- Other

**9. Double contrast barium enema:**

- No
- Yes

If yes:

- Barium
- Complete
- Gastrografine
- Incomplete (incompl. visualisation of the entire colon)

**10. Virtual colonoscopy:**

- No
- Yes

If yes: Simultaneous lesions?

- No
- Polyp
- Carcinoma
- Other

**11. Anorectal function before treatment:**

**Continent?** <sup>REQ</sup>

- Yes
- No

**Daily frequency of defaecation:** .....

**Use of drugs/medication for defaecation (incl. enema)**

- No
- Yes

**12. Urogenital function before treatment:**

a) Urinary function

**Continent?**

- Yes
- No

b) Sexual function

- Non active
- Active

If active:

- Normal
- Dysfunction
- Not known

**13. Clinical restaging after neoadjuvant treatment (if applicable):**

- Date of restaging (dd/mm/yyyy):...../...../.....
- Clinical response (choose 1 of the following)
  - No change in bulk
  - Increase in bulk
  - Reduction in bulk
  - Complete response
- Summary ycTNM: T..... (0,1,2,3,4) N ..... (0,1,2) M ..... (0,1,x)
- ycCRM : ..... mm

## OPERATIVE DATA ENTRY FORM

Registration number, provided by the data centre:.....

Name patient:..... First Name patient:.....

Date of Birth:...../...../.....

### PART II: Operative data

#### 1. WAS RADICAL RESECTION INDICATED BUT NOT PERFORMED? <sup>REQ</sup>

- No
- Yes

**If Yes:** Reason(s):

- Patient unfit
- Patient refusal
- Advanced disease
- Other, please specify: .....

#### 2. TREATMENT OTHER THAN OR PRIOR TO RADICAL RESECTION <sup>REQ</sup>:

- No
- Yes

**If yes:** What treatment(s) was performed instead of or prior to radical resection?

- Abdominal exploration only:
  - Laparotomy
  - Laparoscopy
- Resection of metastatic disease:
  - Liver: date (dd/mm/yy):...../...../.....
  - Lung: date (dd/mm/yy):...../...../.....
  - Brain: date (dd/mm/yy):...../...../.....
  - Bone: date (dd/mm/yy):...../...../.....
  - Other: specify:.....  
date (dd/mm/yy):...../...../.....
- Transanal laser or electrocautery
- Endoscopic stent:
  - As definitive treatment: date (dd/mm/yyyy):...../...../.....
  - As a bridge to surgery: date (dd/mm/yyyy):...../...../.....
- Decompressive stoma:  
Date (dd/mm/yyyy): ...../...../.....  
Approach:
  - Laparotomy:
    - without abdominal exploration
    - with abdominal exploration:
      - no metastatic disease
      - metastatic disease
  - Laparoscopy:
    - without abdominal exploration
    - with abdominal exploration:
      - no metastatic disease
      - metastatic disease



Location:

- Ileum
- Colon transversum
- Sigmoid colon
- other

Type:

- Loop
- Terminal
- "Local excision" (incl. endoscopic polypectomy and TEM):

Procedure:

- Endoscopic polypectomy:  
date (dd/mm/yyyy):...../...../.....  
→ Please fill in 'local excision' pathology report
- Local transanal excision:  
date (dd/mm/yyyy):...../...../.....  
→ Please fill in 'local excision' pathology report
- TEM (transanal endoscopic microsurgery):  
date (dd/mm/yyyy):...../...../.....  
→ Please fill in 'local excision' pathology report

Intent:

- Curative treatment
- Sampling (as an excisional biopsy)
- Neoadjuvant treatment:
  - Short course radiotherapy with short interval to surgery
  - Short course radiotherapy with long interval to surgery
  - Long course chemoradiation with long interval to surgery
  - Long course radiation without chemotherapy
- Chemotherapy for cStage IV disease

**3. RADICAL RESECTION:**

- No
- Yes

**If Yes:**

(Fill in all the following questions 3.1-3.13)

**3.1. PLANNED type of radical resection<sup>REQ.</sup>:**

- Hartmann
- APER
- Sphincter saving radical resection

**3.2. Preoperative risk (factors of):**

**ASA (1-5)<sup>REQ.</sup>** .....

1. normal
2. mild systemic disease, normal activity
3. severe systemic disease, limited activity
4. life threatening disease, disabled
5. moribund

**Hct<sup>REQ.</sup>**: ..... %

**3.3. Preoperative Weight:** .....kg  
**Height:**.....cm

**3.4. Date of surgery (dd/mm/yyyy)** <sup>REQ</sup> :...../...../.....

**3.5 Actual surgical training status:**

- With trainer/instructor
- Self-training
- Peer to peer
- Trainer/instructor

**3.6 Mode of surgery** <sup>REQ</sup>:

- Elective (operation at the time to suit both patient and surgeon)
- Scheduled (an early operation, but not immediately life-saving)
- Urgent (operation carried out within 24-hrs of admission)
- Emergency (immediate operation within 2 hours of admission or in conjunction with resuscitation)

**3.7 Localisation of the primary tumour after anal investigation** <sup>REQ</sup>:

- Ventral
- Lateral left
- Lateral right
- Dorsal
- no evidence of tumour

**3.8 Lower limit of the primary tumour** <sup>REQ</sup> :..... cm above the margo ani  
based on:

- rigid rectoscopy (to be preferred)
- colonoscopy (during withdrawal of the colonoscope)
- no evidence of tumour

**3.9 Rectal irrigation at the start of the surgical procedure:**

- No
- Yes  
If yes:
  - Water
  - Phys Saline Solution
  - Iodine Solution
  - Chlorehexidine
  - Other

**3.10 Surgical exploration**

**Approach:**

- Laparotomy
- Laparoscopy
- Converted laparoscopy: Reason(s):
  - Adhesions
  - Bleeding

- Bowel perforation
- Other, please specify: .....

**Ascites:**

- No
- Yes

Cytology of ascites:

- No
- Yes

**Metastasis** <sup>REQ:</sup>

- No
- Exploration limited because of adherences
- Yes

If yes:

- |   |                                      |                             |
|---|--------------------------------------|-----------------------------|
| <input type="checkbox"/> Liver                        | biopsy: <input type="checkbox"/> yes | <input type="checkbox"/> no |
| <input type="checkbox"/> Peritoneum                   | biopsy: <input type="checkbox"/> yes | <input type="checkbox"/> no |
| <input type="checkbox"/> Omentum                      | biopsy: <input type="checkbox"/> yes | <input type="checkbox"/> no |
| <input type="checkbox"/> Ovary                        | biopsy: <input type="checkbox"/> yes | <input type="checkbox"/> no |
| <input type="checkbox"/> Other (specify) .....        | biopsy: <input type="checkbox"/> yes | <input type="checkbox"/> no |
| <input type="checkbox"/> Non-mesenterial lymph nodes: |                                      |                             |
| <input type="checkbox"/> Iliac                        | biopsy: <input type="checkbox"/> yes | <input type="checkbox"/> no |
| <input type="checkbox"/> Periaortic                   | biopsy: <input type="checkbox"/> yes | <input type="checkbox"/> no |
| <input type="checkbox"/> Hilus liver                  | biopsy: <input type="checkbox"/> yes | <input type="checkbox"/> no |
| <input type="checkbox"/> Celiac                       | biopsy: <input type="checkbox"/> yes | <input type="checkbox"/> no |

**Tumour:**

*Localisation of the tumour related to peritoneal reflection* <sup>REQ:</sup>

- Above
- At the level of
- Under

- Mobile
- Fixed
- Not palpable

*Invasion into other organs* <sup>REQ:</sup>

- No
- Yes

If yes:

- Pelvic wall
- Vagina
- Bladder
- Uterus (and ovaria)
- Prostate
- Seminal vesicle(s)
- Ureter
- Colon

- Small bowel

*Tumour complications before any mobilisation:*

- Peri-rectal abscess
- Stenosis or obstruction
- Free perforation
- Other, please specify: .....

### 3.11 Surgical resection

#### Approach <sup>REQ</sup>:

- Laparotomy
- Laparoscopy
- Converted laparoscopy (intention was to resect laparoscopically):  
Reason(s) for conversion:
  - Adhesions
  - Bleeding
  - Bowel perforation
  - Other, please specify: .....

#### Procedure <sup>REQ</sup>:

##### *Vascular ligatures* <sup>REQ</sup>:

- AMI
- VMI at the level of AMI
- VMI below the pancreas
- ARM
- Other, please specify:.....

##### *Extent of the resection* <sup>REQ</sup>:

‘En bloc’ resection of another organ?

- No
- Yes

##### If yes:

- Pelvic wall
- Vagina
- Bladder
- Uterus (and ovaria)
- Prostate
- Seminal vesicle(s)
- Ureter
- Colon
- Small bowel

Deviation from the procedure of ‘en bloc’ resection? <sup>REQ</sup>

- No
- Yes (why?): .....

Non ‘en bloc’ resection of other organ <sup>REQ</sup>:

- No
- Yes

##### If yes:

- Ovaria

- Liver
- Peritoneum
- Non-mesenterial node(s)
- Other, please specify: .....

*Perforation of the rectum?*<sup>REQ</sup>

- No
- Yes

*Complete resection of the sigmoid?*

- Yes
- No

*Distal level of resection (in case of reconstruction or Hartmann)*<sup>REQ</sup>:

- Rectum: ..... cm above anal verge
- Anorectal (on top of the anal canal)
- Anal (intra-anal)

*Technique used in case of sphincter saving resection*<sup>REQ</sup>:

- PME
- TME
- Conventional

*Technique used in case of APER (abdominoperineal resection):*

- perineal resection in supine position
- perineal resection in prone position

*Autonomous nervous system:*

- Complete preservation
- Section hypogastric at the level of the promontorium
- Section left hypogastric
- Section right hypogastric
- Section pelvic plexus bilateral
- Section pelvic plexus left
- Section pelvic plexus right
- Not known

*Peritoneal washing after resection, before or after reconstruction:*

- No
- Yes

If yes:

- Water
- Phys Saline Solution
- Iodine Solution
- Chlorehexidine
- Other

*Which type of resection is clinically and surgically obtained*<sup>REQ</sup>:

(do not take the results of the pathology report into account)

- R0 (no residual local tumour, no intraoperative rectum perforation, no distant disease)
- R1 (microscopic residual local tumour, or intraoperative rectum

- perforation)
- R2 (macroscopic residual tumour, either locoregional or distal)
- Uncertain: why?
  - Locally
  - At distance

*Problems during resection:*

- No
- Yes (please specify): .....

### 3.12 Surgical reconstruction

**Approach** <sup>REQ:</sup>

- Laparotomy
- Laparoscopy (inc. lap-assisted)
- Converted laparoscopy

*Complete mobilisation of the splenic flexure* <sup>REQ:</sup>

- No
- Yes

*Irrigation of the rectum stump before reanastomosis* <sup>REQ:</sup>

- No
- Yes

If yes:

- Water
- Phys Saline Solution
- Iodine Solution
- Chlorehexidine
- Other

*Type of reconstruction* <sup>REQ:</sup>

- APER (abdominoperineal excision; rectal amputation)
- Hartmann:
  - distal transection level at ..... cm above anal verge
- PME + High anterior resection (= colorectal anastomosis above peritoneal reflection)
- PME + Low anterior resection (= PME + colorectal anastomosis below peritoneal reflection)
- TME + Colon J pouch:
  - length of pouch: .....cm
- TME + Coloplasty:
  - length of incision for plasty: .....cm
- TME + side-to-end coloanal anastomosis
- TME + straight coloanal anastomosis
- TME + Other (specify): .....
- Total excision of colon and rectum with ileal pouch-anal anastomosis
- Total excision of colon and rectum with definitive ileostomy
- Other, please specify: .....

**Distal anastomosis technique** <sup>REQ:</sup>

- Stapled
- Manual

**Derivative stoma after reconstruction (do not fill in in case of APER or Hartmann) <sup>REQ</sup> :**

- No
- Yes

**If yes:**

Place:

- Colon
- Ileum
- Other (specify):.....

Type:

- Loop
- Terminal

Reason(s):

- Routine (if done always with the type of reconstruction)
- Selective (specify reason(s)):
  - ASA 3 or more
  - Difficult dissection
  - 1 l blood transfusion or more
  - Doubtful blood supply
  - Incomplete doughnut
  - Positive leak test
  - Poor bowel preparation
  - Radiotherapy
  - Other (specify): .....

**3.13 Intraoperative bloodtransfusion (not blood loss!) <sup>REQ</sup>:**

- No
- Yes (specify volume of transfused packed cells): ..... ml  
(1 unit PC = 400 ml)

## OPERATIVE DATA ENTRY FORM

Registration number, provided by the data centre:.....

Name patient:..... First Name patient:.....

Date of Birth:...../...../.....

### PART III: Post-operative data

#### 1. Post-operative death <sup>REQ</sup>:

- No
- Yes

If yes:

Date of death (dd/mm/yyyy): ...../...../.....

Cause of death: .....

#### 2. Discharge date (dd/mm/yyyy) <sup>REQ</sup>: ...../...../.....

#### 3. Discharge:

- Home
- Other medical department (incl. geriatric)
- Revalidation centre
- Other, please specify: .....

#### 4. Postoperative bloodtransfusion:

- No
- Yes (specify volume of transfused packed cells):..... ml  
(1 unit PC = 400 ml)

#### 5. Postoperative complications before discharge <sup>REQ</sup> :

- No
- Yes

If yes:

##### a) Medical:

- Pneumonia
- Pulmonary embolism
- Myocardial infarction
- Cerebrovascular accident
- Catheter sepsis
- Renal insufficiency
- Urinary tract infection
- Pyelonephritis
- Deep venous thrombosis
- Other, please specify: .....

##### b) Surgical:

(minor = no reintervention; major = reintervention under narcosis)

- Postoperative bleeding
  - Minor
  - Major



- Ileus (> 4D 'npo')
  - Minor
  - Major
- Urinary retention
- Abdominal wound infection
  - Minor
  - Major
- Perineal wound infection
  - Minor
  - Major
- Deep abscess
  - Minor
  - Major
  
- Leakage of the anastomosis
  - Minor
  - Major

If leakage of the anastomosis: type of the reintervention(s)  
 (fill out numbers chronologically and add dates(dd/mm/yyyy) if applicable):

--	--	--	--	--

1. Derivative stoma construction date:.....
2. Dismantling of anastomosis (Hartmann) date: .....
3. Abdominal drainage date: .....
4. Transanal drainage date: .....
5. Other: .....date: .....

- Complication of the stoma
  - Minor
  - Major

If complication of the stoma: type of complication (with influence on hospitalisation):

- Stoma necrosis
- Retraction
- Prolapse
- Peristomal infection
- Other (specify):.....

If complication of the stoma: type of re-intervention (specify)

.....  
 .....

- Other, please specify: .....

## RADIOTHERAPY DATA ENTRY FORM

Registration number, provided by the data centre:.....

Name patient:..... First Name patient:.....

Date of Birth:...../...../.....

### Treatment <sup>REQ.</sup>:

- Preoperative radiotherapy
- Postoperative radiotherapy

### Concomitant chemotherapy <sup>REQ.</sup>:

- No
- Yes

#### If Yes:

5-FU based ?

- yes
- no

### Treatment position <sup>REQ.</sup>:

- Supine
- Prone

### Belly board <sup>REQ.</sup>:

- Yes
- No

Planned irradiation regimen: ..... x ..... Gy

Date of first irradiation (dd/mm/yyyy) <sup>REQ.</sup>: ...../...../.....

Date of last irradiation (dd/mm/yyyy) <sup>REQ.</sup>: ...../...../.....

Number of fractions <sup>REQ.</sup>: .....

Radiation compliance: treatment interruption of more than five working days <sup>REQ.</sup>:

- No
- Yes

If yes: Reason for treatment interruption of more than 5 working days:

- Toxicity
- Machine break down
- Other (Specify): .....

Total dose given at ICRU reference point <sup>REQ.</sup>: ..... Gy

### Custom shielding <sup>REQ.</sup>:

- MLC
- Blocks
- No

The photon energy used was **REQ**:

- Co<sup>60</sup>
- .....MV

Number of beams used: .....

Technique used **REQ**:

- 2D
- IMRT
- 3D CRT
- IMAT (including VMAT/RapidARC)
- HT (helical tomotherapy)

**Only for 2D planning (simulation)**

Field sizes if 2D: F1: .....cm x .....cm  
F2: .....cm x .....cm

**Applicable for CT-based planning:**

Total volume irradiated to 95% **REQ**: .....cm<sup>3</sup>

PTV: Mean dose **REQ**: .....Gy  
Median dose: .....Gy  
Maximum dose: .....Gy  
Minimum dose: .....Gy

PTV BOOST:

- No **REQ**
- Yes **REQ**

**If yes:**

Mean dose **REQ**: .....Gy  
Median dose: .....Gy  
Maximum dose: .....Gy  
Minimum dose: .....Gy

**Organs at risk (OARs)**

- Small bowel absolute volume (cc) > 15 Gy: ..... cc
- Bladder volume (%) > 40 Gy: ..... %
- Femoral heads combined volume (%) > 40 Gy: ..... %





## CHEMOTHERAPY DATA ENTRY FORM

Registration number, provided by the data centre:.....

Name patient:..... First Name patient:.....

Date of Birth:...../...../.....

### To be filled out at the start of chemotherapy

#### Treatment<sup>REQ</sup> :

- Neoadjuvant chemotherapy:
  - with radiotherapy
  - without radiotherapy
  
- Adjuvant chemotherapy:
  - with radiotherapy
  - without radiotherapy
  
- Palliative chemotherapy:
  - NO surgery planned:
    - because of the extent of the disease
    - because of age and/or comorbidities
    - because of patient refusal
    - other, please specify: .....
  - BEFORE planned surgery for primary, metastatic disease or both (in any sequence)
  - surgery POTENTIALLY planned during/after palliative chemotherapy
  - AFTER resectional surgery of metastasis with following status:
    - R 0 (“no residual disease”)
    - R 1 (at least one resection with a positive margin)
    - R 2 (at least one metastasis present)



**Type of adverse events** during chemotherapy or chemoradiotherapy (mention only grade 3-4 (severe) adverse events to be evaluated according to the NCI-CTC version 3.0 criteria)<sup>REQ</sup> :

- diarrhea:  grade 3  grade 4
- nausea:  grade 3  grade 4
- vomiting:  grade 3  grade 4
- anorexia:  grade 3  grade 4
- neutropenia:  grade 3  grade 4
- neutropenic fever or infection:  grade 3  grade 4
- anemia:  grade 3  grade 4
- thrombocytopenia:  grade 3  grade 4
- stomatitis:  grade 3  grade 4
- neurotoxicity:  grade 3  grade 4
- hand-foot syndrome:  grade 3  grade 4
- other, please specify:.....  
.....

**2. Neoadjuvant chemotherapy without radiotherapy**

- 5 FU: - schedule:
  - bolus
  - continuous infusion
  - planned dose 5FU: ..... mg/m<sup>2</sup>
  - global administered dose 5FU: ..... mg
  - period (date) from ...../...../..... till ...../...../.....
- oral fluoropyrimidines  capecitabine
  - other (please specify):.....
  - planned dose: : ..... mg/m<sup>2</sup>
  - global administered dose: ..... mg
  - period (date) from ...../...../..... till...../...../.....
- other (specify): .....
  - schedule: .....
  - planned dose : ..... mg/m<sup>2</sup>
  - global administered dose: ..... mg
  - period (date) from ...../...../..... till ...../...../.....

**Dose reduction performed:**

- Yes
- No

**Toxicity**<sup>REQ</sup>:

- hospitalisation needed for toxicity exclusively due to chemotherapy
  - Yes, exclusively due to chemotherapy
  - No, other treatment modality contributed also
- leading to stopping chemotherapy
- leading to temporarily interrupting chemotherapy
- leading to dose reduction



**Type of adverse events** during chemotherapy or chemoradiotherapy (mention only grade 3-4 (severe) adverse events to be evaluated according to the NCI-CTC version 3.0 criteria) <sup>REQ.</sup>:

- diarrhea:  grade 3  grade 4
- nausea:  grade 3  grade 4
- vomiting:  grade 3  grade 4
- anorexia:  grade 3  grade 4
- neutropenia:  grade 3  grade 4
- neutropenic fever or infection:  grade 3  grade 4
- anemia:  grade 3  grade 4
- thrombocytopenia:  grade 3  grade 4
- stomatitis:  grade 3  grade 4
- neurotoxicity:  grade 3  grade 4
- hand-foot syndrome:  grade 3  grade 4
- other, please specify:.....  
.....

**3. Adjuvant chemotherapy with radiotherapy**

- 5 FU: - schedule:
  - bolus
  - continuous infusion
  - planned dose 5FU: .....mg/m<sup>2</sup>
  - global administered dose 5FU: .....mg
  - period (date) from ...../...../..... till...../...../.....
- oral fluoropyrimidines  capecitabine
  - other (specify):.....
  - planned dose: .....mg/m<sup>2</sup>
  - global administered dose: ..... mg
  - period (date) from ...../...../..... till ...../...../.....
- other (specify): .....
  - schedule: .....
  - planned dose:.....mg/m<sup>2</sup>
  - global administered dose: ..... mg
  - period (date) from ...../...../..... till ...../...../.....

**Dose reduction performed:**

- Yes
- No

**Toxicity** <sup>REQ.</sup>:

- hospitalisation needed for toxicity exclusively due to chemotherapy
  - Yes, exclusively due to chemotherapy
  - No, other treatment modality contributed also
- leading to stopping chemotherapy
- leading to temporarily interrupting chemotherapy
- leading to dose reduction

**Type of adverse events** during chemotherapy or chemoradiotherapy (mention only grade 3-4 (severe) adverse events to be evaluated according to the NCI-CTC version 3.0 criteria)<sup>REQ.</sup>:

- diarrhea:  grade 3  grade 4
- nausea:  grade 3  grade 4
- vomiting:  grade 3  grade 4
- anorexia:  grade 3  grade 4
- neutropenia:  grade 3  grade 4
- neutropenic fever or infection:  grade 3  grade 4
- anemia:  grade 3  grade 4
- thrombocytopenia:  grade 3  grade 4
- stomatitis:  grade 3  grade 4
- neurotoxicity:  grade 3  grade 4
- hand-foot syndrome:  grade 3  grade 4
- other, please specify:.....  
.....

**4. Adjuvant chemotherapy without radiotherapy**

- 5 FU: - schedule:
  - bolus
  - continuous infusion
  - planned dose 5FU: ..... mg/m<sup>2</sup>
  - global administered dose 5FU: ..... mg
  - period (date) from...../...../..... till ...../...../.....
  
- oral fluoropyrimidines  capecitabine
  - other (specify):.....
  - planned dose: ..... mg/m<sup>2</sup>
  - global administered dose: ..... mg
  - period (date) from ...../...../..... till ...../...../.....
  
- FOLFOX (5FU + Oxaliplatin):
  - 5FU:
    - schedule:
      - bolus
      - continuous infusion
    - planned dose 5FU: ..... mg/m<sup>2</sup>
    - global administered dose 5FU: ..... mg
    - period (date) from ...../...../..... till ...../...../.....
  
  - Oxaliplatin:
    - planned dose oxaliplatin: ..... mg/m<sup>2</sup>
    - global administered dose oxaliplatin: .....mg
    - period (date) from ...../...../..... till ...../...../.....
  
- XELOX:
  - Capecitabine cfr supra:
    - planned dose capecitabine: ..... mg/m<sup>2</sup>
    - global administered dose capecitabine: ..... mg
    - period (date) from ...../...../..... till ...../...../.....

- Oxaliplatin:
  - planned dose oxaliplatin: ..... mg/m<sup>2</sup>
  - global administered dose oxaliplatin: .....mg
  - period (date) from ...../...../..... till ...../...../.....

- Irinotecan:
  - planned dose: ..... mg/m<sup>2</sup>
  - global administered dose: ..... mg
  - period (date) from ...../...../..... till ...../...../.....

- Other (specify): .....
  - schedule: .....
  - planned dose: ..... mg/m<sup>2</sup>
  - global administered dose: ..... mg
  - period (date) from...../...../..... till ...../...../.....

**Dose reduction performed:**

- Yes
- No

**Toxicity<sup>REQ</sup>:**

- hospitalisation needed for toxicity exclusively due to chemotherapy
  - Yes, exclusively due to chemotherapy
  - No, other treatment modality contributed also
- leading to stopping chemotherapy
- leading to temporarily interrupting chemotherapy
- leading to dose reduction

**Type of adverse events** during chemotherapy or chemoradiotherapy (mention only grade 3-4 (severe) adverse events to be evaluated according to the NCI-CTC version 3.0 criteria)<sup>REQ</sup>:

- diarrhea:                      □ grade 3    □ grade 4
- nausea:                        □ grade 3    □ grade 4
- vomiting:                      □ grade 3    □ grade 4
- anorexia:                      □ grade 3    □ grade 4
- neutropenia:                   □ grade 3    □ grade 4
- neutropenic fever or infection:    □ grade 3            □ grade 4
- anemia:                        □ grade 3    □ grade 4
- thrombocytopenia:           □ grade 3    □ grade 4
- stomatitis:                    □ grade 3    □ grade 4
- neurotoxicity:                □ grade 3    □ grade 4
- hand-foot syndrome:        □ grade 3    □ grade 4
- other, please specify:.....
- .....

**5. Palliative chemotherapy (please, use a new form with patient's name or national number for 2<sup>nd</sup> line etc.):**

Regimen	1 <sup>st</sup> line	2 <sup>nd</sup> line	3 <sup>rd</sup> line	4 <sup>th</sup> line
Oral fluoropyrimidine				
LV5FU2 (De Gramont)				
Folfox				
Folfiri				
Xelox				
Oral fluoropyrimidine + bevacizumab				
LV5FU2 (De Gramont) + bevacizumab				
Folfox + bevacizumab				
Folfiri + bevacizumab				
Xelox + bevacizumab				
Cetuximab + irinotecan				
Mitomycine + 5FU or capecitabine				
Other, please specify: .....				

**Dose reduction performed:**

- Yes: percentage: ..... %
- No

**Toxicity<sup>REQ</sup>:**

- hospitalisation needed for toxicity exclusively due to chemotherapy
  - Yes, exclusively due to chemotherapy
  - No, other treatment modality contributed also
- leading to stopping chemotherapy
- leading to temporarily interrupting chemotherapy
- leading to dose reduction

**Type of adverse events** during chemotherapy or chemoradiotherapy (mention only grade 3-4 (severe) adverse events to be evaluated according to the NCI-CTC version 3.0 criteria) <sup>REQ.</sup>:

- diarrhea:  grade 3  grade 4
- nausea:  grade 3  grade 4
- vomiting:  grade 3  grade 4
- anorexia:  grade 3  grade 4
- neutropenia:  grade 3  grade 4
- neutropenic fever or infection:  grade 3  grade 4
- anemia:  grade 3  grade 4
- thrombocytopenia:  grade 3  grade 4
- stomatitis:  grade 3  grade 4
- neurotoxicity:  grade 3  grade 4
- hand-foot syndrome:  grade 3  grade 4
- other (specify):.....  
.....

**Is the patient dead?**

- No
- Yes

If yes:

- death due to chemotherapy alone

- Yes
- No

- death due to chemoradiotherapy

- Yes
- No

**FOLLOW-UP DATA ENTRY FORM**

Registration number, provided by the data centre:.....

Name patient:..... First Name patient:.....

Date of Birth:...../...../.....

**Fill in one form for each follow-up period (i.e. every 6 months regarding to the initial incidence date (with incidence date 1. First histological/cytological confirmation 2. Clinical evaluation/hospitalization 3. First Treatment)).** Indicate the period that is applicable (please choose the period that is closest to the real time-interval) and fill in till 5 year or until an event occurs, i.e. until recurrent local disease or metachronous distant disease or death.

Please, continue follow-up until death for patients with primary cStage IV or pStage IV.

**Follow-up time interval (period) <sup>REQ.</sup>:**

Date of follow-up (dd/mm/yyyy):...../...../.....

- 6 mo
- 12 mo
- 18 mo
- 24 mo
- 30 mo
- 36 mo
- 42 mo
- 48 mo
- 54 mo
- 60 mo
- .....

**1. Did the patient receive chemotherapy in this 6 month interval (period) <sup>REQ.</sup>:**

- No
- Yes

**2. WHO Performance score :**

- 0 = normal activity
- 1 = symptomatic but ambulatory
- 2 = bedridden <50% per day
- 3 = bedridden >50% per day
- 4 = 100% bedridden

**3. LATE COMPLICATIONS OF RADIO and/or CHEMOTHERAPY <sup>REQ.</sup>:**

- No
- Yes

**If yes:** (RTOG/EORTC grading 0-5; fill in max. grade per item)

- Skin: grade: .....
- Gastrointestinal (small/large bowel): grade:.....
- Bladder: grade:.....

- Ureter: grade: .....
- Nerves: grade: .....
- Other (specify+grade): .....

**4. STOMA** <sup>REQ</sup>:

- Not applicable (never had)
- Present
- Closed  
Date closure of stoma (dd/mm/yyyy): ...../...../.....  
(if applicable in this follow-up period)

**5. ANORECTAL FUNCTION:**

**Continent** <sup>REQ</sup>

- Yes
- No
- Not applicable (APER, Hartmann, Derivative stoma)

**Defecation**

Frequency per day or per week: ...../ day or ...../ week

**Medication related to defecation (incl. enemas)**

- No
- Yes, please specify: .....

**6. UROGENITAL FUNCTION as compared with 6 months ago:**

a) Urinary function

- Idem
- Better
- Worse

Specific treatment:

- No
- Yes, please specify:.....

b) Sexual function

- Not active
- Active

If active:

- Idem
- Better
- Worse

Specific treatment:

- No
- Yes, please specify: .....

**7. LATE MEDICAL OR SURGICAL COMPLICATIONS** <sup>REQ</sup> :

*during the preceding 6 months*

- Type (please specify): .....
- Date of diagnosis (dd/mm/yyyy): ...../...../.....
- Treatment (specify briefly): .....
- Comment.....

**8. EXAMINATIONS DONE AT THE OCCASION OF THIS FOLLOW UP <sup>REQ.</sup>:**

**Indicate what was done**

- Colonoscopy  
    If yes, date (dd/mm/yyyy):...../...../.....
- RX thorax
- US liver
- CT abdomen/pelvis
- CT thorax
- CT thorax/abdomen
- PET
- PET/CT
- CEA
- Other(s): .....

**9. NEW PRIMARY TUMOUR <sup>REQ.</sup>:**

- No
- Yes

If yes:

date of diagnosis (dd/mm/yyyy): ...../...../.....

Localisation:

- Colon
- Other (specify): .....

Treatment:

- None
- Chemotherapy
- Radiotherapy
- Radiochemotherapy
- Surgery
- Other, please specify: .....
- Comment.....

**10. LOCAL RECURRENCE <sup>REQ.</sup> (diagnosed in this 6 months interval (period)):**

- No
- Yes

***If yes, this is the final update for the PROCARE registry, but fill in the following***

Date of diagnosis (dd/mm/yyyy): ...../...../.....

Localisation(s): multiple selection possible

- Laparotomy wound
- Trocar (port) site(s)
- Perineal wound
- Small pelvis (excl. external or common iliac lymph nodes)
- External or common iliac nodes
- Other, please specify: .....



Diagnostic proof (check):

- TRUS
- Endoscopy
- Clinical
- CT
- MRI
- Biopsy/cyto
- CEA
- Other, please specify:.....

Treatment:

- None
- Chemotherapy
- Radiotherapy
- Radiochemotherapy
- Surgery
- Palliative measures
- Other, please specify:.....
- Comment.....

**11. METACHRONOUS DISTANT METASTASIS:**

**(metachronous = diagnosed more than 6 months after incidence date i.e. date of diagnosis of rectal cancer) <sup>REQ</sup>**

- no
- yes

***If yes, this is the final update for the PROCARE registry but fill in the following***

Date of diagnosis (dd/mm/yyyy): ...../...../.....

Localisation(s): multiple selection possible

- Liver
- Lung
- Peritoneum
- Para-aortic nodes
- Bone
- Other, please specify: .....

Diagnostic proof (check):

- US
- PET
- RX thorax
- Bone scan
- Clinical
- CT
- MRI
- Biopsy/cyto
- CEA
- Other, please specify: .....

Treatment:

- None
- Chemotherapy
- Radiotherapy
- Radiochemotherapy
- Surgery
- Palliative measures
- Other, please specify: .....
- Comment.....

**12. DEATH:**

- Date (dd/mm/yyyy): ...../...../.....

- Cause (check) **REQ:**

- Cancer related
  - Death related to registered primary
  - Death related to another primary
  - Death related to metastases from unknown origin
- Unknown
- Other, please specify: .....