
SEATTLE CFR CLINICAL DIAGNOSIS AND TREATMENT DATA FORM

SECTION 1. - IDENTIFICATION/MEDICAL RECORDS AVAILABLE FOR ABSTRACTION

CENTER ID: 16

PERSON ID: _____

1.1 Consent for medical records:

1 Yes 2 No

1.2 Medical records sources available for data abstraction [see appendixes A-E]? (Check all that apply):

1 Yes 2 No 3 NA Resection Pathology Report

1 Yes 2 No 3 NA Operative Report

1 Yes 2 No Discharge Summary

1 Yes 2 No Clinical Note(s)

1 Yes 2 No 3 NA Chemotherapy Note(s)

1 Yes 2 No 3 NA Radiotherapy Notes(s)

1 Yes 2 No Any other Radiology report(s) [such as Ultrasound, CT Scan, MRI

Specify _____

1 Yes 2 No Any other report source:

Specify _____

SECTION 2. - BASELINE PRIMARY COLORECTAL CANCER**2.1 First CRC Primary Site: (*If SYNCHRONOUS primaries, please record the LARGEST primary*)**

ICD-O Code_____

Primary Site: ICD-0 Topography (Primary Site) Codes, 3rd Edition:

- C18.0 Cecum; ileocecal valve; ileocecal junction
- C18.1 Appendix
- C18.2 Ascending colon; right colon
- C18.3 Hepatic flexure of colon
- C18.4 Transverse colon
- C18.5 Splenic flexure of colon
- C18.6 Descending colon; Left colon
- C18.7 Sigmoid colon; sigmoid NOS; sigmoid flexure of colon; pelvic colon
- C18.8 Overlapping lesion of colon
- C18.9 Colon, NOS; large intestine; large bowel NOS
- C19.9 Rectosigmoid junction; rectosigmoid, NOS; rectosigmoid colon; colon and rectum; pelvirectal junction
- C20.9 Rectum, NOS; rectal ampulla
- C21.8 Overlapping lesion of rectum, anus and anal canal; anorectal junction; anorectum
- C26.0 Intestinal tract NOS, bowel NOS, intestine NOS
- C80.9 Unknown/Other

2.2 Diagnosis Date Of First CRC Primary(s) in the Eligibility Period

Date_____ (MM/DD/YYYY)

2.3 CSS Tumor Number_____**2.4 Type of surgical treatment** (Can use SEER coding to derive):

- 01 No Surgery – **go to Section 2.14**
- 02 Local tumor destruction, i.e laser, electrocautery
- 03 Local surgical excision with specimen i.e trans-anal excision, polypectomy, snare
- 04 Right Hemi-colectomy
- 05 Left Hemi-colectomy
- 06 Hemi-colectomy – side not specified: not total
- 07 Low anterior Resection
- 08 Total Colectomy
- 09 Total Proctectomy
- 10 Total Proctocolectomy
- 11 Abdominoperineal Resection
- 12 Segmental / Wedge / Partial Resection NOS
- 77 Other Surgery Specify:_____
- 88 Missing (missing document) – **go to Section 2.14**
- 99 Unknown (document available, info missing or uninterpretable) – **go to Section 2.14**

2.5 Date of 1st resection:

Date_____ (MM/DD/YYYY) (Missing = 88/88/8888)

2.6 Hospital at which the surgery was performed:

Name of Hospital_____ Street _____

City_____ State_____ Country_____

(Use 8 if information is missing)

2.7 Operative findings , local (residual tumor)

(obtain information from the operative report and/or the discharge summary- **NOT** pathology report)

- 1 Tumor *not entirely* resected
- 2 Tumor *entirely* resected
- 8 Missing – missing document
- 9 Unknown – document available, info missing or uninterpretable

2.8 Did the tumor reach surgical resection margins? (Source: Pathology report)

- 1 Positive, proximal (Tumor is seen at proximal surgical resection margin)
- 2 Positive, distal (Tumor is seen at distal surgical resection margin)
- 3 Positive, radial (Tumor is seen at radial surgical resection margin)
- 4 Positive, more than one margins defined
- 5 Positive, NOS (Tumor is seen at surgical resection margins, margin not defined)
- 6 Negative (all surgical resection margins are free of tumor)
- 8 Missing (missing document)
- 9 Unknown (document available, info missing or uninterpretable)

2.9 Were other organs (partial or total) removed at definitive surgery?

- 1 Yes
- 2 No - **go to section 2.11**
- 8 Missing (missing document) - **go to section 2.11**
- 9 Unknown (document available, info missing or uninterpretable) - **go to section 2.11**

2.10 If other organs (partial or total) were removed, please specify:

- Small intestine
- Liver
- Appendix (not a part of colon resection)
- Ovary any (side unknown)
- Ovary Right
- Ovary Left
- Ovary Both
- Spleen
- Bladder
- Other Organs Specify: _____

2.11 BASELINE clinicopathologic summary stage of disease. T & N values will be derived from pathology report. To derive M, please use information available from all sources, and all investigations, i.e. resection or biopsy pathology report, pre-operative scan (ultrasound, MRI, CT, nuclear scan), operative notes within 6 months of pathology proven diagnosis date, i.e. 3 months prior/3 months post diagnosis. Please specify source in section 2.15.

Tumor Stage at Baseline

- TIS
- T-1
- T-2
- T-3
- T-4
- 8 Missing
- 9 Unknown

Nodal Stage at Baseline

- N0
- N1
- N2
- 8 Missing
- 9 Unknown

Metastasis Stage at Baseline

- M0
- M1
- 8 Missing
- 9 Unknown

2.12 Source of information for tumor, nodal, and metastasis stage

- 1 Pathology report
 - 2 Clinic Note/Disch Sum
 - 3 Other
- Specify _____
-

- 1 Pathology report
 - 2 Clinic Note/Disch Sum
 - 3 Other
- Specify _____
-

- 1 Pathology report
 - 2 Clinic Note/Disch Sum
 - 3 Operative note
 - 4 Radiology report (US, CT, MRI, etc.)
 - 5 Other
- Specify _____
-

2.13 Operative findings, Distant (obtain info. from the operative report and/or the discharge summary or resection pathology report. Do not record information from radiology reports, i.e. CT scan, Ultrasound, MRI, etc.):

Metastatic Disease Found

- 1 Yes
- 2 No – **go to Section 2.14**
- 8 Missing (missing document) - **go to Section 2.14**
- 9 Unknown (document available, info missing or uninterpretable)- **go to Section 2.14**

Site of Metastatic Disease Found (mark all that apply)

- 1 Ascites
 - 1 Mesenteric lymph nodes, other than in mesentery of planned resection
 - 1 Liver
 - 1 Lung
 - 1 Omentum
 - 1 Abdominal wall
 - 1 Ovary/Ovaries
 - 1 Bone
 - 1 Peritoneum
 - 1 Mesentery
 - 1 Other Specify _____
-

Was this metastasis resected immediately (within 3 months) after baseline surgery?

- 1 All metastases entirely resected
- 2 At least one metastasis not entirely resected
- 3 Not resected (No surgery)
- 8 Missing (missing documentation)
- 9 Unknown (document available, info missing or uninterpretable)

Date metastasis was resected (only if metastasis was completely or incompletely resected)

Date _____ (MM/DD/YYYY) (Missing = 88/88/8888)

2.14 Was chemotherapy given for treatment of the primary colorectal cancer(s)?

- 1 Yes
- 2 No - **go to section 2.18**
- 8 Missing - **go to section 2.18**
- 9 Unknown - **go to section 2.18**

2.15 Date of 1st chemotherapy treatment of the CRC primary(s) in the eligibility period

Date _____ (MM/DD/YYYY) (Missing = 88/88/8888)

2.16 What method of chemotherapy was applied for treatment of the primary colorectal cancer(s)?

- 1 Adjuvant
- 2 Palliative
- 3 Pseudo-Adjuvant
- 4 Neo-Adjuvant (pre-operative)
- 8 Missing (missing document)
- 9 Unknown (document available, info missing or uninterpretable)

2.17 CHEMOTHERAPEUTIC AGENT - FOR BASELINE DIAGNOSIS - first course only. (If agent is not listed please refer to last page to add it.)

	DRUG_DESC
<input type="checkbox"/>	5 FU / FLUOROURACIL/ ADRUCIL
<input type="checkbox"/>	FA (FOLINIC ACID) / LEUCOVORIN / WELLCOVORIN
<input type="checkbox"/>	CPT11/ IRINOTECAN / CAMPTOSAR
<input type="checkbox"/>	TOMUDEX
<input type="checkbox"/>	OXALIPLATIN / ELOXATIN
<input type="checkbox"/>	LEVAMISOLE
<input type="checkbox"/>	GEMZAR
<input type="checkbox"/>	CISPLATINUM / CISPLATIN
<input type="checkbox"/>	RALTITREXED
<input type="checkbox"/>	ETOPISADE
<input type="checkbox"/>	XELODA / CAPECITABINE
<input type="checkbox"/>	EPOTHILONE
<input type="checkbox"/>	AVASTIN / BEVACIZUMAB
<input type="checkbox"/>	ERBITUX/ CETUXIMAB
<input type="checkbox"/>	VECTIBIX / PANITUMUMAB
<input type="checkbox"/>	UNKNOWN

2.18 Was radiation given for treatment of the primary colorectal cancer(s)?

- 1 Yes
- 2 No - **go to section 2.21**
- 8 Missing - **go to section 2.21**
- 9 Unknown - **go to section 2.21**

2.19 Date of 1st radiotherapy treatment of the CRC primary(s) in the eligibility period

Date _____ (MM/DD/YYYY) (Missing = 88/88/8888)

Dose of radiotherapy treatment

_____ CGY

2.20 What method of radiotherapy was applied for treatment of the primary colorectal cancer(s)?

- 1 Adjuvant
- 2 Palliative
- 3 Pseudo-Adjuvant
- 4 Neo-Adjuvant (pre-operative)
- 8 Missing (missing document)
- 9 Unknown (document available, info missing or uninterpretable)

2.21 Were other treatment methods applied for primary colorectal cancer(s)?

1 Yes – Specify

Treatment 1: _____ Treatment 2: _____

2 No

8 Missing (not documented/relevant)

9 Unknown (document available, info missing or uninterpretable)

SYNCHRONOUS PRIMARY(S)

2.22 2nd Synchronous Primary Diagnosed?

1 Yes

2 No - **go to section 3**

8 Missing - **go to section 3**

9 Unknown - **go to section 3**

2.23 2nd SYNCHRONOUS CRC PRIMARY DIAGNOSIS TYPE. Please record the 2nd largest. (PRIMARY_2)

ICD-O Code _____

2.24 DIAGNOSIS DATE OF 2nd SYNCHRONOUS CRC PRIMARY IN THE ELIGIBILITY PERIOD

Date _____ (MM/DD/YYYY) (Missing = 88/88/8888)

2.25 CSS Tumor Number _____

2.26 Surgical treatment for 2nd synchronous primary CRC (Can use SEER coding to derive)

01 No surgery – **go to section 2.30**

02 Local tumor destruction, i.e laser, electrocautery

03 Local surgical excision with specimen i.e trans-anal excision, polypectomy, snare

04 Right Hemi-colectomy

05 Left Hemi-colectomy

06 Hemi-colectomy – side not specified: not total

07 Low anterior Resection

08 Total Colectomy

09 Total Proctectomy

10 Total Proctocolectomy

11 Abdominoperineal Resection

12 Segmental / Wedge / Partial Resection NOS

77 Other Surgery Specify: _____

88 Missing (missing document) - **go to section 2.30**

99 Unknown (document available, info missing or uninterpretable) - **go to section 2.30**

2.27 Date of 2nd synchronous primary resection

Date _____ (MM/DD/YYYY) (Missing = 88/88/8888)

2.28 Operative findings , local (residual tumor)

(obtain information from the operative report and/or the discharge summary- **NOT** pathology report)

1 Tumor *not entirely* resected

2 Tumor *entirely* resected

8 Missing (missing document)

9 Unknown (document available, info missing or uninterpretable)

2.29 Did the tumor reach surgical resection margins? (Source: Pathology report)

- 1 Positive, proximal (Tumor is seen at proximal surgical resection margin)
- 2 Positive, distal (Tumor is seen at distal surgical resection margin)
- 3 Positive, radial (Tumor is seen at radial surgical resection margin)
- 4 Positive, more than one margins defined
- 5 Positive, NOS (Tumor is seen at surgical resection margins, margin not defined)
- 6 Negative (all surgical resection margins are free of tumor)
- 8 Missing (missing document)
- 9 Unknown (document available, info missing or uninterpretable)

2.30 3rd Synchronous Primary Diagnosed?

- 1 Yes
- 2 No - **go to section 3**
- 8 Missing - **go to section 3**
- 9 Unknown - **go to section 3**

2.31 3rd SYNCHRONOUS CRC PRIMARY DIAGNOSIS TYPE. Please record the 3rd largest. (PRIMARY_3)

ICD-O Code_____

2.32 DIAGNOSIS DATE OF 3rd SYNCHRONOUS CRC PRIMARY IN THE ELIGIBILITY PERIOD

Date_____ (MM/DD/YYYY) (Missing = 88/88/8888)

2.33 CSS Tumor Number_____

2.34 Surgical treatment for 3rd synchronous primary CRC (Can use SEER coding to derive)

- 01 No surgery – **go to section 3**
- 02 Local tumor destruction, i.e laser, electrocautery
- 03 Local surgical excision with specimen i.e trans-anal excision, polypectomy, snare
- 04 Right Hemi-colectomy
- 05 Left Hemi-colectomy
- 06 Hemi-colectomy – side not specified: not total
- 07 Low anterior Resection
- 08 Total Colectomy
- 09 Total Proctectomy
- 10 Total Proctocolectomy
- 11 Abdominoperineal Resection
- 12 Segmental / Wedge / Partial Resection NOS
- 77 Other Surgery Specify:_____
- 88 Missing (missing document) - **go to section 3**
- 99 Unknown (document available, info missing or uninterpretable) - **go to section 3**

2.35 Operative findings , local (residual tumor)

(obtain information from the operative report and/or the discharge summary- **NOT** pathology report)

- 1 Tumor *not entirely* resected
- 2 Tumor *entirely* resected
- 8 Missing (missing document)
- 9 Unknown (document available, info missing or uninterpretable)

2.36 Did the tumor reach surgical resection margins? (Source: Pathology report)

- 1 Positive, proximal (Tumor is seen at proximal surgical resection margin)
- 2 Positive, distal (Tumor is seen at distal surgical resection margin)
- 3 Positive, radial (Tumor is seen at radial surgical resection margin)
- 4 Positive, more than one margins defined
- 5 Positive, NOS (Tumor is seen at surgical resection margins, margin not defined)
- 6 Negative (all surgical resection margins are free of tumor)
- 8 Missing (missing document)
- 9 Unknown (document available, info missing or uninterpretable)

CLINICAL FOLLOW-UP SINCE BASELINE DIAGNOSIS

(At Least 4 Years after the Incident Colorectal Cancer Diagnosis)

SECTION 3 - FIRST LOCOREGIONAL RECURRENCE

3.1. Did the patient have at least one locoregional recurrence after CRC diagnosis? (Ideally interval between diagnosis date and final chart review date should be at least 4 years)

- 1 Yes
- 2 No - **go to section 4**
- 8 Missing (missing document) - **go to section 4**
- 9 Unknown (document available, info missing or uninterpretable) - **go to section 4**

3.2. Site(s) of involvement at time of first locoregional recurrence (please mark all that apply): (provide date of diagnosis from the most reliable data source in this order: pathology, autopsy, operative note, clinical note, discharge summary)

<u>Yes</u>	<u>No</u>	<u>Miss.</u>	<u>Unk.</u>	<u>LocoRegional Recurrence Site</u>	<u>First Diagnosed</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Anastomosis	Date_____ (MM/DD/YYYY)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Mesentery	Date_____ (MM/DD/YYYY)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Abdominal wall (not incisional)	Date_____ (MM/DD/YYYY)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Incisional	Date_____ (MM/DD/YYYY)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Pelvis	Date_____ (MM/DD/YYYY)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Other site – Specify	Date_____ (MM/DD/YYYY)
				_____	Date_____ (MM/DD/YYYY)
				_____	Date_____ (MM/DD/YYYY)

3.3 Surgical treatment given for locoregional recurrence?

- 1 Yes
- 2 No - **go to section 3.6**
- 8 Missing (missing document) - **go to section 3.6**
- 9 Unknown (document available, info missing or uninterpretable) - **go to section 3.6**

3.4 Surgery for locoregional recurrence:

- 1 Recurrent tumor *entirely* resected
- 2 Tumor *not entirely* resected
- 8 Missing (missing document) - **go to section 3.6**
- 9 Unknown (document available, info missing or uninterpretable) - **go to section 3.6**

3.5 If 3.4 = 1 or 2, then specify (describe procedure—text format)

Description _____

3.6 Was chemotherapy given for locoregional recurrence?

- 1 Yes
- 2 No - **go to section 3.10**
- 8 Missing (missing document) - **go to section 3.10**
- 9 Unknown (document available, info missing or uninterpretable) - **go to section 3.10**

3.7 What method of chemotherapy was applied for treatment of the locoregional recurrence(s)

- 1 Adjuvant
- 2 Palliative
- 3 Pseudo-Adjuvant
- 4 Neo-Adjuvant (pre-operative)
- 8 Missing (missing document)
- 9 Unknown (document available, info missing or uninterpretable)

3.8 Date of 1st chemotherapy treatment of the locoregional recurrence.

Date _____ (MM/DD/YYYY) (Missing = 88/88/8888)

3.9 CHEMOTHERAPEUTIC AGENT - FOR 1st locoregional recurrence - first course only. (If agent is not listed please refer to last page to add it.)

	DRUG_DESC
<input type="checkbox"/>	5 FU / FLUOROURACIL/ ADRUCIL
<input type="checkbox"/>	FA (FOLINIC ACID) / LEUCOVORIN / WELLCOVORIN
<input type="checkbox"/>	CPT11/ IRINOTECAN / CAMPTOSAR
<input type="checkbox"/>	TOMUDEX
<input type="checkbox"/>	OXALIPLATIN / ELOXATIN
<input type="checkbox"/>	LEVAMISOLE
<input type="checkbox"/>	GEMZAR
<input type="checkbox"/>	CISPLATINUM / CISPLATIN
<input type="checkbox"/>	RALTITREXED
<input type="checkbox"/>	ETOPISADE
<input type="checkbox"/>	XELODA / CAPECITABINE
<input type="checkbox"/>	EPOTHILONE
<input type="checkbox"/>	AVASTIN / BEVACIZUMAB
<input type="checkbox"/>	ERBITUX/ CETUXIMAB
<input type="checkbox"/>	VECTIBIX / PANITUMUMAB
<input type="checkbox"/>	UNKNOWN

3.10 Was radiotherapy given for locoregional recurrence?

- 1 Yes
- 2 No - **go to section 3.13**
- 8 Missing - **go to section 3.13**
- 9 Unknown - **go to section 3.13**

Dose of radiotherapy treatment

_____ CGY

3.11 What method of radiotherapy was applied for treatment of the locoregional recurrence?

- 1 Adjuvant
- 2 Palliative
- 3 Pseudo-Adjuvant
- 4 Neo-Adjuvant (pre-operative)
- 8 Missing (missing document)
- 9 Unknown (document available, info missing or uninterpretable)

3.12 Date of 1st radiotherapy treatment of the locoregional recurrence.

Date _____ (MM/DD/YYYY) (Missing = 88/88/8888)

3.13 Were other treatment methods applied for first locoregional recurrence?

- 1 Yes – Specify
Treatment 1: _____ Treatment 2: _____
- 2 No
- 8 Missing (not documented/relevant)
- 9 Unknown (document available, info missing or uninterpretable)

3.14 Locoregional recurrence site(s) after the 1st site(s) identified – This records when there is a locoregional recurrence after the first recurrence was identified with/without treatment. Record only when there is a clear evidence for more than 1 site: (please provide date of recurrence diagnosis from the most reliable report source in order of preference: pathology, autopsy, operative note, clinical note, radiological investigations, discharge summary)

<u>Yes</u>	<u>No</u>	<u>Miss.</u>	<u>Unk.</u>	<u>LocoRegional Recurrence Site</u>	<u>First Diagnosed</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Anastomosis	Date _____ (MM/DD/YYYY)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Mesentery	Date _____ (MM/DD/YYYY)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Abdominal wall (not incisional)	Date _____ (MM/DD/YYYY)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Incisional	Date _____ (MM/DD/YYYY)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Pelvis	Date _____ (MM/DD/YYYY)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Other site – Specify _____	Date _____ (MM/DD/YYYY)
				_____	Date _____ (MM/DD/YYYY)

SECTION 4 - FIRST DISTANT RECURRENCE**4.1. Did the patient have a distant recurrence after CRC diagnosis (after start date to final chart date available)?**

- 1 Yes
- 2 No - **go to section 5**
- 8 Missing (missing document) - **go to section 5**
- 9 Unknown (document available, info missing or uninterpretable) - **go to section 5**

4.2. Site(s) of involvement at time of first distant recurrence (please check off all that apply): (please provide date of diagnosis from the most reliable data source in this order: pathology, autopsy, operative note, clinical note, discharge summary)

Yes	No	Miss.	Unk.	Distant Recurrence Site	First Diagnosed
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Liver	Date_____ (MM/DD/YYYY)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Lung	Date_____ (MM/DD/YYYY)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Bone	Date_____ (MM/DD/YYYY)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Ascites	Date_____ (MM/DD/YYYY)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Non-mesenteric lymph nodes (except supraclavicular) - Specify	_____ Date_____ (MM/DD/YYYY)
					_____ Date_____ (MM/DD/YYYY)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Supraclavicular nodes	Date_____ (MM/DD/YYYY)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Brain	Date_____ (MM/DD/YYYY)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Skin, except incision - Specify	_____ Date_____ (MM/DD/YYYY)
					_____ Date_____ (MM/DD/YYYY)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Adrenal gland	Date_____ (MM/DD/YYYY)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Other site – Specify	_____ Date_____ (MM/DD/YYYY)
					_____ Date_____ (MM/DD/YYYY)

4.3. Did the patient undergo treatment for distant recurrence?:

- 1 Yes
- 2 No - **go to section 4.14**
- 8 Missing (missing document) - **go to section 4.14**
- 9 Unknown (document available, info missing or uninterpretable) - **go to section 4.14**

4.4 Did patient undergo surgical treatment for distant recurrence?

- 1 Yes
- 2 No - **go to section 4.7**
- 8 Missing (missing document) - **go to section 4.7**
- 9 Unknown (document available, info missing or uninterpretable) - **go to section 4.7**

4.5 Surgery for distant recurrence:

- 1 Recurrent tumor *entirely* resected
- 2 Recurrent tumor *not entirely* resected
- 8 Missing (missing document) – **go to section 4.7**
- 9 Unknown (document available, info missing or uninterpretable) – **go to section 4.7**

4.6 If 4.5 = 1 or 2, then specify (describe procedure-text format):

Description _____

4.7 Did patient undergo chemotherapy for distant recurrence?

- 1 Yes
- 2 No - **go to section 4.11**
- 8 Missing (missing document) - **go to section 4.11**
- 9 Unknown (document available, info missing or uninterpretable) - **go to section 4.11**

4.8 If chemotherapy was given, what method of chemotherapy was applied for treatment of the distant recurrence?

- 1 Adjuvant
- 2 Palliative
- 3 Pseudo-Adjuvant
- 4 Neo-Adjuvant (pre-operative)
- 8 Missing (missing document)
- 9 Unknown (document available, info missing or uninterpretable)

4.9 Date of 1st chemotherapy treatment of the distant recurrence.

Date _____ (MM/DD/YYYY) (Missing = 88/88/8888)

4.10 CHEMOTHERAPEUTIC AGENT - FOR 1st distant recurrence - first course only. (If agent is not listed please refer to last page to add it.)

	DRUG_DESC
<input type="checkbox"/>	5 FU / FLUOROURACIL/ ADRUCIL
<input type="checkbox"/>	FA (FOLINIC ACID) / LEUCOVORIN / WELLCOVORIN
<input type="checkbox"/>	CPT11/ IRINOTECAN / CAMPTOSAR
<input type="checkbox"/>	TOMUDEX
<input type="checkbox"/>	OXALIPLATIN / ELOXATIN
<input type="checkbox"/>	LEVAMISOLE
<input type="checkbox"/>	GEMZAR
<input type="checkbox"/>	CISPLATINUM / CISPLATIN
<input type="checkbox"/>	RALTITREXED
<input type="checkbox"/>	ETOPISADE
<input type="checkbox"/>	XELODA / CAPECITABINE
<input type="checkbox"/>	EPOTHILONE
<input type="checkbox"/>	AVASTIN / BEVACIZUMAB
<input type="checkbox"/>	ERBITUX/ CETUXIMAB
<input type="checkbox"/>	VECTIBIX / PANITUMUMAB
<input type="checkbox"/>	UNKNOWN

4.11 Was radiotherapy treatment given for distant recurrence?

- 1 Yes
- 2 No - **go to section 4.14**
- 8 Missing (missing document) - **go to section 4.14**
- 9 Unknown (document available, info missing or uninterpretable) - **go to section 4.14**

Dose of radiotherapy

_____ CGY

4.12 What method of radiotherapy was applied for treatment of the 1st distant recurrence?

- 1 Adjuvant
- 2 Palliative
- 3 Pseudo-Adjuvant
- 4 Neo-Adjuvant (pre-operative)
- 8 Missing (missing document)
- 9 Unknown (document available, info missing or uninterpretable)

4.13 Date of 1st radiotherapy treatment of the distant recurrence.

Date _____ (MM/DD/YYYY) (Missing = 88/88/8888)

4.14 Distant recurrence site(s) after the 1st site(s) identified – This records when there is a distant recurrence after the first recurrence was identified with/without treatment. Record only when there is a clear evidence for more than 1 site: (please provide date of recurrence diagnosis from the most reliable report source in order of preference: pathology, autopsy, operative note, clinical note, radiological investigations, discharge summary)

<u>Yes</u>	<u>No</u>	<u>Miss.</u>	<u>Unk.</u>	<u>Distant Recurrence Site</u>	<u>First Diagnosed</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Liver	Date _____ (MM/DD/YYYY)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Lung	Date _____ (MM/DD/YYYY)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Bone	Date _____ (MM/DD/YYYY)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Ascites	Date _____ (MM/DD/YYYY)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Non-mesenteric lymph nodes (except supraclavicular) - Specify	_____ Date _____ (MM/DD/YYYY)
					_____ Date _____ (MM/DD/YYYY)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Supraclavicular nodes	Date _____ (MM/DD/YYYY)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Brain	Date _____ (MM/DD/YYYY)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Skin, except incision - Specify	_____ Date _____ (MM/DD/YYYY)
					_____ Date _____ (MM/DD/YYYY)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Adrenal gland	Date _____ (MM/DD/YYYY)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Other site – Specify	_____ Date _____ (MM/DD/YYYY)
					_____ Date _____ (MM/DD/YYYY)

SECTION 5 - NEW PRIMARY COLORECTAL CANCER

5.1 Did the patient have a new primary colorectal cancer diagnosis after the original CRC diagnosis (after start date to final chart date)?

- 1 Yes - **go to section 5.2**
- 2 No - **go to section 6**
- 8 Missing (missing document) - **go to section 6**
- 9 Unknown (document available, info missing or uninterpretable) - **go to section 6**

5.2 PRIMARY DIAGNOSIS TYPE. If SYNCHRONOUS primaries, please record the LARGEST. (NEW_PRIMARY_1)

ICD-O Code _____

5.3 DIAGNOSIS DATE OF 1st New CRC PRIMARY IN THE ELIGIBILITY PERIOD

Date _____ (MM/DD/YYYY) (Missing = 88/88/8888)

5.4 CSS Tumor Number _____

5.5 Type of surgical treatment for new primary colorectal cancer (Can use SEER coding)

- 01 No surgery – **go to section 5.15**
- 02 Local tumor destruction, i.e laser, electrocautery
- 03 Local surgical excision with specimen i.e trans-anal excision, polypectomy, snare
- 04 Right Hemi-colectomy
- 05 Left Hemi-colectomy
- 06 Hemi-colectomy – side not specified: not total
- 07 Low anterior Resection
- 08 Total Colectomy
- 09 Total Proctectomy
- 10 Total Proctocolectomy
- 11 Abdominoperineal Resection
- 12 Segmental / Wedge / Partial Resection NOS
- 77 Other Surgery Specify: _____
- 88 Missing (missing document) - **go to section 5.15**
- 99 Unknown (document available, info missing or uninterpretable) - **go to section 5.15**

5.6 Date of 1st resection for new primary CRC:

Date _____ (MM/DD/YYYY) (Missing = 88/88/8888)

5.7 Hospital at which the surgery for new primary CRC was performed:

Name of Hospital _____ Street _____

City _____ State _____ Country _____

(Use 8 if information is missing)

5.8 Operative findings , local (residual tumor)

(obtain information from the operative report and/or the discharge summary- **NOT** pathology report)

- 1 Tumor *not entirely* resected
- 2 Tumor *entirely* resected
- 8 Missing (missing document)
- 9 Unknown (document available, info missing or uninterpretable)

5.9 Did the tumor reach surgical resection margins? (Source: Pathology report)

- 1 Positive, proximal (Tumor is seen at proximal surgical resection margin)
- 2 Positive, distal (Tumor is seen at distal surgical resection margin)
- 3 Positive, radial (Tumor is seen at radial surgical resection margin)
- 4 Positive, more than one margins defined
- 5 Positive, NOS (Tumor is seen at surgical resection margins, margin not defined)
- 6 Negative (all surgical resection margins are free of tumor)
- 8 Missing (missing document)
- 9 Unknown (document available, info missing or uninterpretable)

5.10 Were other organs (partial or total) removed at definitive surgery?

- 1 Yes
- 2 No – **go to Section 5.12**
- 8 Missing (missing document) - **go to Section 5.12**
- 9 Unknown (document available, info missing or uninterpretable) - **go to Section 5.12**

5.11 If other organs were removed (partial or total), specify:

- Small intestine
- Liver
- Appendix (not a part of colon resection)
- Ovary any (side unknown)
- Ovary Right
- Ovary Left
- Ovary Both
- Spleen
- Bladder
- Other Organs Specify: _____
- Missing (missing document)

5.12 Clinicopathologic summary stage of disease. T & N values will be derived from pathology report. To derive M, please use information available from all sources, and all investigations, i.e. resection or biopsy pathology report, pre-operative scan (ultrasound, MRI, CT, nuclear scan), operative notes within 6 months of pathology proven diagnosis date, i.e. 3 months prior/3 months post diagnosis. Please specify source in section 5.7

Tumor Stage at Baseline

- TIS
- T-1
- T-2
- T-3
- T-4
- 8 Missing
- 9 Unknown

Nodal Stage at Baseline

- N0
- N1
- N2
- 8 Missing
- 9 Unknown

Metastasis Stage at Baseline

- M0
- M1
- 8 Missing
- 9 Unknown

5.13 Source of information for tumor, nodal, and metastasis stage

- 1 Pathology report
 - 2 Clinic Note/Disch Sum
 - 3 Other
- Specify _____
-

- 1 Pathology report
 - 2 Clinic Note/Disch Sum
 - 3 Other
- Specify _____
-

- 1 Pathology report
 - 2 Clinic Note/Disch Sum
 - 3 Operative note
 - 4 Radiology report (US, CT, MRI, etc.)
 - 5 Other
- Specify _____
-

5.14 Was distant metastatic disease found at surgery? (Obtain info. from the operative report and/or the discharge summary or resection pathology report. **Do not record information from radiology reports, i.e. CT scan, Ultrasound, MRI, etc.):**

Metastatic Disease Found

- 1 Yes
- 2 No – **go to Section 5.15**
- 8 Missing (missing document) - **go to Section 5.15**
- 9 Unknown (document available, info missing or uninterpretable) - **go to Section 5.15**

Site of Metastatic Disease Found (mark all that apply)

- 1 Ascites
 - 1 Mesenteric lymph nodes, other than in mesentery of planned resection
 - 1 Liver
 - 1 Lung
 - 1 Omentum
 - 1 Abdominal wall
 - 1 Ovary/Ovaries
 - 1 Bone
 - 1 Peritoneum
 - 1 Mesentery
 - 1 Other Specify _____
-

Was this metastasis resected immediately (within 3 months) after baseline surgery?

- 1 All metastases entirely resected
- 2 At least one metastasis not entirely resected
- 3 Not resected (No surgery)
- 8 Missing (missing documentation)
- 9 Unknown (document available, info missing or uninterpretable)

Date metastasis was resected (only if metastasis was completely or incompletely resected)

Date _____ (MM/DD/YYYY) (Missing = 88/88/8888)

5.15 Was chemotherapy given for treatment of the new primary colorectal cancer(s)?

- 1 Yes
- 2 No - **go to section 5.19**
- 8 Missing (missing document) - **go to section 5.19**
- 9 Unknown (document available, info missing or uninterpretable) - **go to section 5.19**

5.16 Date of 1st chemotherapy treatment of the CRC primary(s) in the eligibility period

Date _____ (MM/DD/YYYY) (Missing = 88/88/8888)

Dose of radiotherapy

_____ CGY

5.17 What method of chemotherapy was applied for treatment of the new primary colorectal cancer(s)?

- 1 Adjuvant
- 2 Palliative
- 3 Pseudo-Adjuvant
- 4 Neo-Adjuvant (pre-operative)
- 8 Missing (missing document) - **go to section 5.19**
- 9 Unknown (document available, info missing or uninterpretable) - **go to section 5.19**

5.18 CHEMOTHERAPEUTIC AGENT - FOR new CRC DIAGNOSIS First course only. (If agent is not listed please refer to last page to add it.)

	DRUG_DESC
<input type="checkbox"/>	5 FU / FLUOROURACIL/ ADRUCIL
<input type="checkbox"/>	FA (FOLINIC ACID) / LEUCOVORIN / WELLCOVORIN
<input type="checkbox"/>	CPT11/ IRINOTECAN / CAMPTOSAR
<input type="checkbox"/>	TOMUDEX
<input type="checkbox"/>	OXALIPLATIN / ELOXATIN
<input type="checkbox"/>	LEVAMISOLE
<input type="checkbox"/>	GEMZAR
<input type="checkbox"/>	CISPLATINUM / CISPLATIN
<input type="checkbox"/>	RALTITREXED
<input type="checkbox"/>	ETOPISADE
<input type="checkbox"/>	XELODA / CAPECITABINE
<input type="checkbox"/>	EPOTHILONE
<input type="checkbox"/>	AVASTIN / BEVACIZUMAB
<input type="checkbox"/>	ERBITUX/ CETUXIMAB
<input type="checkbox"/>	VECTIBIX / PANITUMUMAB
<input type="checkbox"/>	UNKNOWN

5.19 Was radiation given for treatment of the new primary colorectal cancer(s)?

- 1 Yes
- 2 No - **go to section 5.22**
- 8 Missing (missing document) - **go to section 5.22**
- 9 Unknown (document available, info missing or uninterpretable) - **go to section 5.22**

5.20 Date of 1st radiotherapy treatment of the CRC primary(s) in the eligibility period

Date _____ (MM/DD/YYYY) (Missing = 88/88/8888)

5.21 What method of radiotherapy was applied for treatment of the new primary colorectal cancer(s)?

- 1 Adjuvant
- 2 Palliative
- 3 Pseudo-Adjuvant
- 4 Neo-Adjuvant (pre-operative)
- 8 Missing (missing document)
- 9 Unknown (document available, info missing or uninterpretable)

5.22 Were other treatment methods applied for new primary colorectal cancer(s)?

1 Yes – Specify

Treatment 1: _____ Treatment 2: _____

2 No – **go to section 5.23**

8 Missing (not documented/relevant) - **go to section 5.23**

9 Unknown (document available, info missing or uninterpretable) - **go to section 5.23**

SYNCHRONOUS PRIMARY(S)

5.23 2nd Synchronous Primary Diagnosed:

1 Yes

2 No - **go to section 6**

8 Missing (missing document) - **go to section 6**

9 Unknown (document available, info missing or uninterpretable) - **go to section 6**

5.24 2nd SYNCHRONOUS CRC PRIMARY DIAGNOSIS TYPE. (Please record the 2nd largest. (NEW_PRIMARY_2))

ICD-O Code _____

5.25 DIAGNOSIS DATE OF 2nd SYNCHRONOUS CRC PRIMARY IN THE ELIGIBILITY PERIOD

Date _____ (MM/DD/YYYY) (Missing = 88/88/8888)

5.26 CSS Tumor Number _____

5.27 Surgical treatment for 2nd synchronous CRC (Can use SEER coding to derive)

01 No surgery – **go to section 5.31**

02 Local tumor destruction, i.e laser, electrocautery

03 Local surgical excision with specimen i.e trans-anal excision, polypectomy, snare

04 Right Hemi-colectomy

05 Left Hemi-colectomy

06 Hemi-colectomy – side not specified: not total

07 Low anterior Resection

08 Total Colectomy

09 Total Proctectomy

10 Total Proctocolectomy

11 Abdominoperineal Resection

12 Segmental / Wedge / Partial Resection NOS

77 Other Surgery Specify: _____

88 Missing (missing document) - **go to section 5.31**

99 Unknown (document available, info missing or uninterpretable) - **go to section 5.31**

5.28 Date of 2nd resection for new primary CRC:

Date _____ (MM/DD/YYYY) (Missing = 88/88/8888)

5.29 Operative findings , local (residual tumor)

(obtain information from the operative report and/or the discharge summary- **NOT** pathology report)

1 Tumor *not entirely* resected

2 Tumor *entirely* resected

8 Missing (missing document)

9 Unknown (document available, info missing or uninterpretable)

5.30 Did the tumor reach surgical resection margins? (Source: Pathology report)

- 1 Positive, proximal (Tumor is seen at proximal surgical resection margin)
- 2 Positive, distal (Tumor is seen at distal surgical resection margin)
- 3 Positive, radial (Tumor is seen at radial surgical resection margin)
- 4 Positive, more than one margins defined
- 5 Positive, NOS (Tumor is seen at surgical resection margins, margin not defined)
- 6 Negative (all surgical resection margins are free of tumor)
- 8 Missing (missing document)
- 9 Unknown (document available, info missing or uninterpretable)

5.31 3rd Synchronous Primary Diagnosed:

- 1 Yes
- 2 No - **go to section 6**
- 8 Missing (missing document) - **go to section 6**
- 9 Unknown (document available, info missing or uninterpretable) - **go to section 6**

5.32 3rd SYNCHRONOUS CRC PRIMARY DIAGNOSIS TYPE. (Please record the 3rd largest. (NEW_PRIMARY_3)

ICD-O Code_____

5.33 DIAGNOSIS DATE OF 3rd SYNCHRONOUS CRC PRIMARY IN THE ELIGIBILITY PERIOD

Date_____ (MM/DD/YYYY) (Missing = 88/88/8888)

5.34 CSS Tumor Number_____

5.35 Surgical treatment for 3rd SYNCHRONOUS CRC primary (Can use SEER coding to derive)

- 01 No surgery – **go to section 6**
- 02 Local tumor destruction, i.e laser, electrocautery
- 03 Local surgical excision with specimen i.e trans-anal excision, polypectomy, snare
- 04 Right Hemi-colectomy
- 05 Left Hemi-colectomy
- 06 Hemi-colectomy – side not specified: not total
- 07 Low anterior Resection
- 08 Total Colectomy
- 09 Total Proctectomy
- 10 Total Proctocolectomy
- 11 Abdominoperineal Resection
- 12 Segmental / Wedge / Partial Resection NOS
- 77 Other Surgery Specify:_____
- 88 Missing (missing document) - **go to section 6**
- 99 Unknown (document available, info missing or uninterpretable) - **go to section 6**

5.36 Date of 3rd resection for new primary CRC:

Date_____ (MM/DD/YYYY) (Missing = 88/88/8888)

5.37 Operative findings , local (residual tumor)

(obtain information from the operative report and/or the discharge summary- **NOT** pathology report)

- 1 Tumor *not entirely* resected
- 2 Tumor *entirely* resected
- 8 Missing (missing document)
- 9 Unknown (document available, info missing or uninterpretable)

5.38 Did the tumor reach surgical resection margins? (Source: Pathology report)

- 1 Positive, proximal (Tumor is seen at proximal surgical resection margin)
- 2 Positive, distal (Tumor is seen at distal surgical resection margin)
- 3 Positive, radial (Tumor is seen at radial surgical resection margin)
- 4 Positive, more than one margins defined
- 5 Positive, NOS (Tumor is seen at surgical resection margins, margin not defined)
- 6 Negative (all surgical resection margins are free of tumor)
- 8 Missing (missing document)
- 9 Unknown (document available, info missing or uninterpretable)

SECTION 6 - NEW PRIMARY NON-COLORECTAL CANCER

6.1 Did the proband have a new primary non-colorectal cancer diagnosis after the original CRC diagnosis (after incident CRC date to date of final chart note)

- 1 Yes
- 2 No
- 8 Missing (missing document) - **go to section 7**
- 9 Unknown (document available, info missing or uninterpretable) - **go to section 7**

SECTION 7 - FINAL REVIEW

DEATH

7.1 Did the proband expire after CRC diagnosis (after incident CRC date to date of final chart note)

- 1 Yes – Patient died because of colorectal cancer
- 2 Yes – Patient died of causes other than colorectal cancer
- 3 Yes – Patient died, cause of death unknown
- 4 No – Patient is alive - **go to section 7.3**
- 5 Missing (missing document) - **go to section 7.3**

7.2 What was the patient's cause of death? (if known use ICD code)

ICD Code_____

ICD Code_____

ICD Code_____

ICD Code_____

LAST MEDICAL RECORD

7.3 Date of Last (Most Recent) Physician Chart Note found by the Abstractor (Operative Notes, Discharge Summary, Clinic Notes, Chemotherapy and/or Radiotherapy Notes)

Date _____ (MM/DD/YYYY)

7.4 Status at time of Last Chart Note or Medical Report

- 1 Alive, cancer free
- 2 Alive, with cancer
- 3 Deceased (as per section 7.1)
- 8 Missing (missing document)
- 9 Unknown (document available, info missing or uninterpretable)

7.5 Date Form Completed (date review/abstraction completed)

Date _____ (MM/DD/YYYY)

7.6 Date of last FU Treatment contact with participant or next of kin:

Date _____ (MM/DD/YYYY)

2.17 Chemotherapeutic Agent – For Baseline Diagnosis – first course only

	DRUG_DESC
<input type="checkbox"/>	
<input type="checkbox"/>	
<input type="checkbox"/>	
<input type="checkbox"/>	

3.9 Chemotherapeutic Agent – For 1st locoregional recurrence – first course only

	DRUG_DESC
<input type="checkbox"/>	
<input type="checkbox"/>	
<input type="checkbox"/>	
<input type="checkbox"/>	

4.10 Chemotherapeutic Agent – For 1st distant recurrence – first course only

	DRUG_DESC
<input type="checkbox"/>	
<input type="checkbox"/>	
<input type="checkbox"/>	
<input type="checkbox"/>	

5.18 Chemotherapeutic Agent – FOR new CRC Diagnosis – first course only

	DRUG_DESC
<input type="checkbox"/>	
<input type="checkbox"/>	
<input type="checkbox"/>	
<input type="checkbox"/>	