All doses capped: Min 0.1 mg – Max 1000 mg

Absolute doses non-obligatory

Adverse Event Forms and automatic notifications implemented

Metastatic Pancreatic Adenocarcinoma Research

Patient Record (PR)

Version R – July 7th 2016 – Post pilots

Prepared for Baxalta

Introduction

[SHOW ALL - Reconnection]

Dear Doctor,

Thank you for connecting to our study.

To proceed to the questions, please click button to accept the conditions.

CONFIDENTIALITY AGREEMENT: You acknowledge that in the course of this study, proprietary information regarding products and product development, and other trade secrets and know-how may be disclosed, and by participating in this study you agree to hold all such information confidential and to not disclose it to any third party or use it for any other purpose whatsoever. You also agree not to disclose any part of the following pages, which is proprietary material of Genactis and its client. You are required to accept the above confidentiality agreement in order to participate in this survey. Please indicate whether or not you accept:

1. Yes	**[CONTINUE]**
2. No	**[TERMINATE]**

PATIENT RECORD

[SHOW ALL]

Thank you for completing this questionnaire. You will now be directed to the Patient Record (PR) section.

The data you will provide in these records will help us to better understand your current and past treatment of metastatic pancreatic cancer patients.

Please enter data for your **last** **[12 in EU5 countries and 3-8 in Nordics and in NL] patients diagnosed with metastatic pancreatic adenocarcinoma**, who meet the following criteria:

For patients to be eligible for their patient record (PR) to be reported, the patient must:

- Be 18 years of age or older **and**
- Be diagnosed with metastatic pancreatic adenocarcinoma **and**
- Must have completed a first line anti-cancer treatment for metastatic disease within the last 6 to 24 months (between July 2014 and January 2016) (whether patients are currently alive or dead, and whether they still receive active treatment or not).

Please do not select any cases as this may compromise our effort to obtain a sample that accurately represents your routine metastatic pancreatic adenocarcinoma patient load. Please report each patient only once. We do need to collect a representative proportion of 1st, 2nd and more line patients.

[STUDY BOARD – THIS IS A PAGE THAT DOCTORS SEE EVERYTIME THEY RE-CONNNECT, AS A REMINDER]

Dear Doctor,

The study-board below shows your progress towards completing your PRs.

For each completed PR a summary of key patient characteristics will be listed under "Patient description". This will help you to avoid entering the details for a patient more than once or to refer back to the right patient cases in the (hypothetical) event of any follow-up queries.

Please ensure you have extracted / have ready access to the relevant information from the patient´s records prior to commencing completion of the online form.

[ACTIVE BUTTON: "Click here to enter a patient"]		
Anonymous Patient list	**Patient description** (year of birth / gender / current line of therapy/ most recent therapy received)	**Date of PR completion** **(dd/mm/yyyy)**

For patients to be eligible for their patient record (PR) to be reported, the patient must:

- Be 18 years of age or older **and**
- Be diagnosed with metastatic pancreatic adenocarcinoma **and**
- Must have completed a first line anti-cancer treatment for metastatic disease within the last 6 to 24 months (whether patients are currently alive or dead, and whether they still receive active treatment or not).

[HOOK WITH PATIENT SCREENER]

Doctor you indicated that in the last 24 months, **[RECALL SQ6]** of your patients received a first line and **[RECALL SQ7]** received a second line.

Please make sure you enter all of your 2nd Line patients.

[SHOW ALL] SECTION 1 –UP TO PAGE 15

E0. Doctor can you please confirm that the patient you are about to enter fulfil the following criteria:

- Be 18 years of age or older **and**
- Be diagnosed with metastatic pancreatic adenocarcinoma **and**
- Must have completed a first line anti-cancer treatment for metastatic disease within the last 6 to 24 months (whether patients are currently alive or dead, and whether they still receive active treatment or not).

Yes to all above criteria	**1**
No	**2 [If No, show error message "**Doctor, this patient is not eligible for reporting an EPR**" and go back to Study Board]**

E1. Date of patient's last visit (DD/MM/YYYY): |_|_| |_|_| |_|_|_|_|

[Min Value = 01/06/2014, Max Value = Today]

E2. Gender:

Male	**1**
Female	**2**

E3. Current status of the patient

Alive	**1**
Dead	**2**

E4. Date of birth DD/MM/YYYY |_|_| |_|_| |_|_|_|_|

[Min=1/5/1998 and Max=1/12/1916]

[SHOW IF E3=2]

E4_1. Date of death (DDMMYYYY) |_|_| |_|_| |_|_|_|_|

[Min 1/05/2014 and Max today] [IF E4_1 <E1 show error message]

[SHOW if E3=1]

E3a. What is the current treatment status?

Completed 1st line metastatic treatment and no active treatment any longer / Best Supportive Care only	**1**
Completed 1st line metastatic treatment ; waiting to start 2nd line	**2**
In 2nd line metastatic treatment	**3**
Completed 2nd line and no active treatment after 2nd line / Best Supportive Care only	**4**
Completed 2nd line; waiting to start 3rd line metastatic treatment	**5**
In 3rd line metastatic treatment	**6**
Completed 3rd line and no active treatment after 3rd line / Best Supportive Care only	**7**
Completed 3rd line; waiting to start 4th line metastatic treatment	**8**
In 4th and more line metastatic treatment or waiting to start 5th or more line metastatic treatment	**9**
No active treatment after 4th or more line metastatic treatment any longer / Best Supportive Care only	**10**

[SHOW if E3=2]

E3b. What was the last known line of therapy for this patient?

In 1st line metastatic treatment	**1**
Completed 1st line metastatic treatment and no active treatment planned / Was in Best Supportive Care	**2**
Completed 1st line metastatic treatment ; was waiting to start 2nd line	**3**
In 2nd line metastatic treatment	**4**
Completed 2nd line metastatic treatment and no active treatment planned / Was in Best Supportive Care	**5**
Completed 2nd line; was waiting to start 3rd line metastatic treatment	**6**
In 3rd line metastatic treatment	**7**
Completed 3rd line metastatic treatment and no active treatment planned / Was in Best Supportive Care	**8**
Completed 3rd line; was waiting to start 4th line metastatic treatment	**9**
In 4th and more line metastatic treatment or was waiting to start 5th or more line metastatic treatment	**10**
No active treatment after 4th or more line metastatic treatment planned / Was in Best Supportive Care only	**11**

Diagnosis and treatment

[SHOW ALL]

E5. Date of initial diagnosis of pancreatic cancer: ⌊_⌊_⌋⌊_⌊_⌋⌊_⌊_⌊_⌊_⌋

[Min Value = 1/1/1980, Max Value = E5]

E5_1. Was the patient diagnosed with metastatic disease at the same date?

	Tick only one
Yes	○ **1**
No	○ **2**

[HIDE IF E5_1=1]

E6. Date when patient was diagnosed with metastatic disease: ⌊_⌊_⌋⌊_⌊_⌋⌊_⌊_⌊_⌊_⌋

[Min Value > =E5, Max Value = 1/10/2015]

[SHOW ALL]

E7. Patient weight at diagnosis of pancreatic cancer: ⌊_⌊_⌋ Kg

Min Value=40, Max Value =140

E8. Patient height

_ _ cm (140 to 210)	**[Minimum=140, Maximum=210]** **If out of range value, SHOW ERROR MESSAGE:** Could you please check your answer?

E9. Symptoms present at initial diagnosis

	Tick all that apply
Weight loss	A
Jaundice	B
Dark urine	C
Steatorrhea	D
Itching	E
Nausea	F
Vomiting	G
Abdominal pain	H
Mid back pain	I
Bloating	J
Depression	K
Deep vein thrombosis	L
Recent unexpected onset of diabetes not associated with weight gain or familial history	M
Cachexia	N
Diarrhea	O
Other (specify) [INSERT OPEN END]	P

[SHOW ALL]

E10. Performance status at initial diagnosis

ECOG Grade	Karnofsky Grade	Tick only one
0	100	○ 1
1	80-90	○ 2
2	60-70	○ 3
3	40-50	○ 4
4	10-30	○ 5
Unknown		○ 6

For details on the ECOG and Karnofsky Grade, please click here. [INSERT LINK – APPENDIX 1]

E11. Please indicate level at initial diagnosis

				To be programmed	
			Tick if not performed	MIN	MAX
1	CA19-9	_____ U/ml		0	5000
2	Albumin	_____ g/l		15 g/l	80 g/l
3	Bilirubin	_____ IU/L _____ µmol/		0.1 IU/l 5 µmol /l	30,000 IU/L 700 µmol/l

IF OUTSIDE RANGES: Can you please confirm this value?

YES / NO [IF YES GO TO NEXT QUESTION, IF NO GO BACK TO E11]

[SHOW ALL]

E12. How was initial diagnosis established? (please tick all that apply)

	Tick all that apply
CT Scan	A
MRI	B
EUS (Endoscopic ultrasound)	C
ERCP (Endoscopic retrograde cholangiography and pancreatography)	D
Core needle biopsy (CNB)	E
Biopsy of primary tumour	F
Biopsy of metastases	G
Other [If ticked show open answer] Please specify:_____	H

E13. Location of primary tumour within the pancreas

	Tick only one
Head	○ 1
Body	○ 2
Tail	○ 3
Head/Body	○ 4
Body/Tail	○ 5
Don´t know	○ 6

[SHOW all]

E14. Indicate the subtype of adenocarcinoma

	Tick only one
Ductal adenocarcinoma	○1
Intraductal papillary adenocarcinoma	○ 2
Cystadenocarcinoma	○ 3
Other	○ 4
Unknown	○ 5

E14_1. Indicate

	Tick only one
Genetic form	○1
Non-genetic form	○ 2

E15. Indicate Grading

	Tick only one
G1	○1
G2	○ 2
G3	○ 3
Unknown	○ 4

[HIDE IF E5_1=1]

E16. Stage of pancreatic cancer at initial diagnosis

	Tick only one
Stage 0 (Tis, N0, M0)	○1
Stage IA (T1, N0, M0)	○ 2
Stage IB (T2, N0, M0)	○ 3
Stage IIA (T3, N0, M0)	○ 4
Stage IIB (T1-3, N1, M0)	○ 5
Stage III (T4, any N, M0)	○ 6
Stage IV (any T, any N, M1)	○ 7
Unstaged / don´t know	○ 8

[SHOW ALL]

E17. Please indicate the type of invasion at initial diagnosis:

	Tick all that apply
Perineural	A
Vascular	B
Lymphatic	C
Mixed	D
Other	E
Unknown / not available	F
Not applicable	G

[SHOW if E16= 1,2,3,4,5, 6, or 8)]

E18. IF non metastatic disease, was the primary tumour resectable?

	Tick only one
Resectable	○ **1**
Borderline resectable	○ **2**
Locally advanced unresectable [SHOW IF E16=4, 5 OR 6 OR 8]	○ **3**

[SHOW IF E18= 1 OR 2]

E19. Has the primary tumour been resected?

	Tick only one
Yes	○ **1**
No	○ **2**

E19_1. [SHOW IF E19= 2]

Why was the primary tumour not resected?

	Tick all that apply
Not considered resectable before surgery (tumour growth or progression e.g.)	A
Not considered resectable after neoadjuvant treatment (tumour not shrunken, tumour growth or progression e.g.)	B
During exploration not considered resectable	C
Patient´s preference	D
Frailty	E
Age	F
Medical contraindication for surgery	G
Performance status	H
Other. [If ticked show open answer] Please specify:_____	I

[SHOW IF E19 =1]

E19_2. What was the outcome of the resection?

	Tick only one
R0	○ 1
R1	○ 2
R2	○ 3
Outcome unknown	○ 4

[SHOW IF E19 =1]

E19_3. Date of the resection |_|_| |_|_| |_|_|

[Min Value = E5, Max Value = E6]

[SHOW IF E18= 1 OR 2]

E20. Did the patient receive neoadjuvant therapy?

	Tick only one
Yes	○ **1**
No	○ **2**

[SHOW if E20= 1]

E20_1. Did the patient receive radiotherapy in neoadjuvant treatment?

	Tick only one
Yes	○ **1**
No	○ **2**

[SHOW IF E19= 1]

E21. Did the patient receive adjuvant therapy following surgery?

	Tick only one
Yes	○ **1**
No	○ **2**

[SHOW IF E20=1] SECTION 2 –UP TO PAGE 28

NEOADJUVANT TREATMENT

E22. Start date of treatment (DD/MM/YYYY)

|__|__| |__|__| |__|__|__|__|

[Min E5 ; Max E19_3] [OR max E6 if no resection]

E23. End date of the treatment (DD/MM/YYYY)

|__|__| |__|__| |__|__|__|__|

[Min >=E22; Max E19_3] [OR max E6 if no resection]

E24. What chemotherapeutic treatment did the patient receive as neoadjuvant therapy? Please select if one of the regimen below was used

	Tick only one
FOLFIRINOX (5-FU/LV – irinotecan - oxaliplatin)	○ **1**
mFOLFIRINOX (5-FU/LV – irinotecan - oxaliplatin)	○ **2**
FOLFOX4 (oxaliplatin - 5-FU/LV)	○ **3**
FOLFOX6 (oxaliplatin - 5-FU/LV)	○ **4**
mFOLFOX6 (oxaliplatin - 5-FU/LV)	○ **5**
FOLFOX7 (oxaliplatin - 5-FU/LV)	○ **6**
mFOLFOX7 (oxaliplatin - 5-FU/LV)	○ **7**
OFF (oxaliplatin - 5-FU/LV)	○ **8**
FOLFIRI-1 (irinotecan - 5-FU/LV)	○ **9**
FOLFIRI-3 (irinotecan - 5-FU/LV)	○ **10**
IFF (irinotecan - 5-FU/LV)	○ **11**
5-FU/LV	○ **12**
Capecitabine - oxaliplatin	○ **13**
Capecitabine monotherapy	○ **14**
Gemcitabine - nab-paclitaxel	○ **15**
Gemcitabine - erlotinib	○ **16**
Gemcitabine – capecitabine	○ **17**
Gemcitabine - oxaliplatin	○ **18**
Gemcitabine - cisplatin	○ **19**
Gemcitabine monotherapy	○ **20**
None of the above	○ **21**

[Show if E24 = 21]

E25. Please select what chemotherapeutic treatment the patient received as neoadjuvant therapy.

Select as many agents as it applies. If you only select one compound, we understand that you used it in monotherapy.

	Tick all that apply
Paclitaxel	**A**
Gemcitabine	**B**
Capecitabine	**C**
nab-paclitaxel	**D**
5-FU/LV	**E**
Irinotecan	**F**
Cisplatin	**G**
Oxaliplatin	**H**
S1	**I**
Erlotinib	**J**
Other specify_____	**K [Insert Open end]**
Other specify_____	**L [Insert Open end]**
Other specify_____	**M [Insert Open end]**
Other specify_____	**N [Insert Open end]**
Other specify_____	**o[Insert Open end]**

IF E25K, E25L E25M, E25N OR E25 O = nal-IRI or Onivid or MM-398 HOOK for potential AE

[SHOW IF E24=1 to 12] [All doses MIN 0.1 – MAX

E24_0. Confirmation of regimens (selected in E24)

E24_1	**Please confirm the regimen**	**Absolute dose given in the first cycle (Please indicate for each product)**
FOLFIRINOX **SHOW IF E24=1]**	Oxaliplatin 85mg/m2 IV d1; LV 400 mg/m2 IV d1; Irinotecan 180mg/m2 IV d1; 5-FU 400mg/m2 bolus d1; 5-FU 2400mg/m2 civ d1 over 46 h, every 2 weeks ☐ I confirm I used the above regimen **[show absolute dose column]** ☐ I did not use exactly this regimen **[GO TO E26 (dosing changes)**	**Oxaliplatin _____ mg** **LV_____ mg** **5FU_____ mg** **Irinotecan_____ mg** **GO TO E27**
mFOLFIRINOX **SHOW IF E24=2]**	☐ Oxaliplatin 85mg/m2 IV d1; LV 400 mg/m2 IV d1; Irinotecan 180mg/m2 IV d1; 5-FU 2400mg/m2 civ d1 over 46 h, every 2 weeks **[If ticked show absolute dose column]** ☐ Oxaliplatin 85 mg/m2 IV 2h; LV 400 mg/m2 IV 2h; Irinotecan 135 mg/m2 IV 1,5h; 5-FU 300mg/m2 IV bolus, then 2400 mg/m2 civ over 46h, every 2 weeks **[If one of the above option ticked, then show absolute dose column]** ☐ I did not use any of these regimens **[GO TO E26 (dosing changes)**	**Oxaliplatin _____ mg** **LV_____ mg** **5FU_____ mg** **Irinotecan_____ mg** **GO TO E27**
FOLFOX4 **SHOW IF E24=3]**	Oxaliplatin 85 mg/m2 IV 2h d1; LV 200 mg/m2 IV 2h d1 and 2; 5-FU 400 mg/m2 bolus + 600 mg/m2 civ 22h d1 and 2, every 2 weeks ☐ I confirm I used the above regimen **[show absolute dose column]** ☐ I did not use exactly this regimen **[GO TO E26 (dosing changes)**	**Oxaliplatin _____ mg** **LV_____ mg** **5FU_____ mg** **GO TO E27**
FOLFOX6 **SHOW IF E24=4]**	Oxaliplatin 100 mg/m² IV 2h d1 and 2; LV 400 mg/m² IV 2h d1 and 2; 5-FU 400 mg/m² bolus d1 and 2; 5-FU 2400 mg/m² civ 46h every 2 weeks. ☐ I confirm I used the above regimen [show absolute dose column] ☐ I did not use exactly this regimen [**GO TO E26 (dosing changes)**)	**Oxaliplatin _____ mg** **LV_____ mg** **5FU_____ mg** **GO TO E27**

mFOLFOX6	oxaliplatin 85 mg/m2 IV d1; LV 200 mg/m2 d1, 5-FU 400 mg/m2 bolus d1 + 2,400 mg/m2 civ 46h, every 2 weeks ☐ I confirm I used the above regimen [show absolute dose column]	**Oxaliplatin _____ mg** **LV_____ mg** **5FU_____ mg**

SHOW IF E24=5]	☐ I did not use exactly this regimen [**GO TO (E26 (dosing changes)**	**GO TO E27**
FOLFOX7 **SHOW IF E24=6]**	oxaliplatin 130 mg/m2 IV 2h d1; LV 400 mg/m2 IV 2h d1; 5-FU 400 mg/m2 bolus d1; 5-FU 2,400 mg/m2 civ 46h, every 2 weeks ☐ I confirm I used the above regimen [show absolute dose column] ☐ I did not use exactly this regimen [**GO TO (E26 (dosing changes)**	**Oxaliplatin _____ mg** **LV_____ mg** **5FU_____ mg** **GO TO E27**
mFOLFOX7 **SHOW IF E24=7]**	oxaliplatin 85 mg/m2 IV 2h d1; LV 200 mg/m2 IV 2h d1; 5-FU 2400 mg/m2 civ 46h, every 2 weeks ☐ I confirm I used the above regimen [show absolute dose column] ☐ I did not use exactly this regimen [**GO TO (E26 (dosing changes)**	**Oxaliplatin _____ mg** **LV_____ mg** **5FU_____ mg** **GO TO E27**
OFF **SHOW IF E24=8]**	Oxaliplatin 85 mg/m2 IV d8 and 22; 5-FU 2000 mg/m2 civ 24h d1, 8, 15, 22; LV 200 mg/m2 IV d1, 8, 15, and 22, every 6 weeks. ☐ I confirm I used the above regimen [**show absolute dose column]** ☐ I did not use exactly this regimen **[GO TO (E26 (dosing changes)**	**Oxaliplatin _____ mg** **LV_____ mg** **5FU_____ mg** **GO TO E27**
FOLFIRI-1 **SHOW IF E24=9]**	Irinotecan 180 mg/m 2 IV d1; LV 400 mg/m 2 IV d1; 5-FU 400 mg/m 2 IV bolus d1; 5-FU 2400 mg/m 2 civ 46, every 2 weeks ☐ I confirm I used the above regimen [**show absolute dose column]** ☐ I did not use exactly this regimen **[GO TO (E26 (dosing changes)**	**Irinotecan _____ mg** **LV_____ mg** **5FU_____ mg** **GO TO E27**
FOLFIRI-3 **SHOW IF E24=10]**	irinotecan 100 mg/m 2 IV d1; LV 400 mg/m 2 IV d1; 5-FU 2000 mg/m 2 civ 46, every 2 weeks ☐ I confirm I used the above regimen [**show absolute dose column]** ☐ I did not use exactly this regimen **[GO TO (E26 (dosing changes)**	**Irinotecan _____ mg** **LV_____ mg** **5FU_____ mg** **GO TO E27**
5FU / LV **SHOW IF E24=12]**	☐ **de Gramont** LV 200 mg/m2 IV bolus, 5-FU bolus 400 mg/m2 IV; 5-FU 600 mg/m2 civ d1 and 2, every 2 weeks ☐ **Mayo clinic regimen** 5-FU 425 mg/m2 IV bolus d1-5; LV 20 mg/m2 IV bolus d1-5, every 4 weeks ☐ **Nordic FLV** 5-FU 500 mg/m2 bolus; LV 60 mg/m2 d1 and 2, every 2 weeks	**LV_____ mg** **5FU_____ mg** **GO TO E27**

	[If one of the above option ticked, then show absolute dose column] ☐ Other 5FU/LV regimens [**GO TO (E26 (dosing changes)**	

[SHOW IF E20=1] [SHOW IF E24=11 to 21 AND E25 ticked]

FOR PROGRAMMING PURPOSES, EACH REGIMEN IN E24 IS SPLIT INTO E25 VARIABLES.

E26. INITIAL DOSE AND FREQUENCY REGIMEN

To be reported in all other dosing tables	Dose: [Only one unit per dose / compulsory]	Frequency	Other Frequency (not listed), please specify	Absolute dose given in the first cycle
Paclitaxel SHOW IF E25=A]	Dose: _____ □ mg / m2	□ weekly □ every 3 weeks □ other (specify)	Open-end	Total mg _____ mg
Gemcitabine SHOW IF E25=B]	Dose: _____ □ mg / m2	□ once weekly week 1-7 (rest week 8), followed by once weekly week 1-3 every 4 weeks □ day 1, 8 and 15 every 4 weeks □ day 1 and 8 every 3 weeks □ day 1 and 15 every 4 weeks □ other (specify)	Open-end	Total mg _____ mg
Capecitabine SHOW IF E25=C]	Dose: _____ □ mg / m2 If flat dose is used, please tick: □ mg	□ twice daily d1-d14 every 3 weeks □ twice daily d1-d21 every 3 weeks □ other (specify)	Open-end	Total mg _____ mg
Nab-paclitaxel SHOW IF E25=D]	Dose: _____ □ mg / m2	□ day 1, 8 and 15 every 4 weeks □ other (specify)	Open-end	Total mg _____ mg
5-FU civ SHOW IF E25=E	Dose: _____ □ mg / m2 Other unit, please tick: □ mg / kg	□ 22h infusion every 2 weeks □ 46h infusion every 2 weeks □ 72h infusion every 2 weeks □ 24h infusion week 1-4 every 6 weeks □ other (specify)	Open-end	Total mg _____ mg [compulsory]
5-FU BOLUS SHOW IF E25=E	Dose: _____ □ mg / m2	□ d1 every 2 weeks □ d1 and 2 every 2 weeks □ d1-5 every 4 weeks	Open-end	Total mg _____ mg [compulsory]

		☐ once weekly week 1-4 every 6 weeks ☐ once weekly week 1-6 every 8 weeks ☐ other (specify)		
Leucovorin SHOW IF E25=E	**Dose: _____** ☐ **mg / m2**	☐ **d1 every 2 weeks** ☐ **d1 and 2 every 2 weeks** ☐ **d1-5 every 4 weeks** ☐ **once weekly week 1-4 every 6 weeks** ☐ **once weekly week 1-6 every 8 weeks** ☐ **other (specify)**	**Open-end**	**Total mg** **_____ mg**
Irinotecan SHOW IF E25=F	**Dose: _____** ☐ **mg / m2** **Other unit, please tick:** ☐ **mg**	☐ **d1 every 2 weeks** ☐ **d1 every 3 weeks** ☐ **d1 and 3 every 2 weeks** ☐ **once weekly week 1-4 every 6 weeks** ☐ **d1 and 15 every 4 weeks** ☐ **other (specify)**	**Open-end**	**Total mg** **_____ mg**
Cisplatin SHOW IF E25=G]	**Dose: _____** ☐ **mg / m2**	☐ **d1 and 15 every 4 weeks** ☐ **once every 3 weeks** ☐ **once every 4 weeks** ☐ **other (specify)**	**Open-end**	**Total mg** **_____ mg**
Oxaliplatin SHOW IF E25=H]	**Dose: _____** ☐ **mg / m2**	☐ **d1 every 2 weeks** ☐ **d1 and 2 every 2 weeks** ☐ **d1 every 3 weeks** ☐ **once weekly week 1, 3 and 5, every 8 weeks** ☐ **other (specify)**	**Open-end**	**Total mg** **_____ mg**
S-1 SHOW IF E25=I]	**Dose: _____** ☐ **mg / m2**	☐ **twice daily d1-28 every 6 weeks** ☐ **other (specify)**	**Open-end**	**Total mg** **_____ mg**
Erlotinib	**Dose:** **_____**	☐ **Daily** ☐ **other (specify)**	**Open-end**	**Total mg**

SHOW IF E25=J	☐ **mg**			**_____ mg**
[RECALL OTHERS] SHOW IF E25=K, L, M, N, O]	**Dose:** **_____** **Dosing unit:** ☐ **mg / m2** ☐ **mg** ☐ **mg / Kg**	**Frequency, please specify** **Open-end**	**Open-end**	**Total mg** **_____ mg**

[SHOW IF E20=1]

E27. How many cycles of the neoadjuvant therapy/ies listed above did the patient receive? ☐☐

[MIN 1 - MAX 10]

[SHOW IF E20=1]

E28. Was the initial regimen modified (doses, delays, compound stopped)?

	TICK ONLY ONE
YES, it was modified	
NO, it was maintained all through the entire neoadjuvant treatment	

[SHOW IF E28=1]

E29. DOSING / TREATMENT CHANGES

Doctor, you mentioned that there were modifications/delays in the therapy, please indicate what product and in which cycle there were changes:

SHOW AS MANY COLUMNS AS E27

Tick all that apply – At least one tick

SHOW PRODUCTS SELECTED (E24 /) E25	Cycle 1	Cycle 2	Cycle 3	Cycle 4	Etc.		
Product 1	AA	BA	CA	DA			
Product 2	AB	BB	CB	DB			
Product 3	AC	BC	CC	DC			
Product 4	AD	BD	CD	DD			
Etc.							

[SHOW IF E28=1] [NEXT SCREEN]

E30. Doctor, you mentioned that there were modifications in the therapy please indicate for each product and cycle the modifications.

RECALL E29	**Tick all that apply**	**Specify**	**Total absolute dose for this cycle**
Eg. IF AA TICKED **Product 1, cycle 1**	Dose delayed ○ **A**	By how many days the dose was delayed_____	
	Dose modified ○ **B**	**RECALL PREVIOUS DOSE** Enter the new dose_____	_____ Total mg Tick box if other dosing unit: _____**INSERT OPEN END**
	Product stopped ○ **C**		
Etc.			

[SHOW IF E30=C TICKED] - FOR EACH PRODUCT SELECTED

E31. Why was one or more compounds stopped?

	Tick all that apply
Dose-limiting toxicity / Side effects	**A**
Prevention of future toxicity / Side effects (not yet dose-limiting before) per physician´s guidance	**B**
Prevention of future toxicity / Side effects (not yet dose-limiting before) per patient's or family's decision	**C**
Maximum cumulative dose reached	**D**
Logistical reasons (hospital planning related)	**E**
Logistical reasons (patient´s or family´s request)	**F**
Lack of efficacy / No anti-tumour value of continued treatment per physician´s guidance	**G**
No overall value of continued treatment (overall risk-benefit) per physician´s guidance	**H**
No overall value of continued treatment (overall risk-benefit) per patient's/family's decision	**I**
Other	**J**

IF E25K, E25L E25M, E25N OR E25 O = nal-IRI or Onivid or MM-398
AND E31=A OR G THEN Display Adverse Event Forms

[SHOW IF E30=A TICKED] FOR EACH PRODUCT SELECTED

E32. Why was dose delayed?

	Tick all that apply
Dose-limiting toxicity / Side effects	**A**
Prevention of future toxicity / Side effects (not yet dose-limiting before) per physician´s guidance	**B**
Prevention of future toxicity / Side effects (not yet dose-limiting before) per patient's or family's decision	**C**
Logistical reasons (hospital planning related)	**D**
Logistical reasons (patient´s or family´s request)	**E**
Other	**F**

IF E25K, E25L E25M, E25N OR E25 O = nal-IRI or Onivid or MM-398 AND E32=A THEN Display Adverse Event Forms

[SHOW IF E30=B TICKED] FOR EACH PRODUCT SELECTED

E33. Why were doses modified?

	Tick all that apply
Dose-limiting toxicity / Side effects	**A**
Prevention of future toxicity / Side effects (not yet dose-limiting before) per physician´s guidance	**B**
Prevention of future toxicity / Side effects (not yet dose-limiting before) per patient's or family's decision	**C**
No overall value of continued full treatment (overall risk-benefit) per physician´s guidance	**D**
No overall value of continued full treatment (overall risk-benefit) per patient's/family's decision	**E**
Other	**F**

IF E25K, E25L E25M, E25N OR E25 O = nal-IRI or Onivid or MM-398 AND E33=A THEN Display Adverse Event Forms

[SHOW IF E20=1]

E34. Was this neoadjuvant treatment given in the context of a Clinical Trial?

	Tick only one
Yes	○ **1**
No	○ **2**

[SHOW IF E20=1]

E35. What was the outcome of this treatment?

	Tick only one
Tumour down-sized and resectable	○ **1**
Tumour down-sized and still borderline resectable	○ **2**
Primary tumour progression	○ **4**
Metastatic disease	○ **5**

[SHOW IF E20=1]

E36. Why was the neoadjuvant treatment stopped?

	Tick all that apply
Toxicity / Side effects	**A**
Prevention of future toxicity / side-effects	**B**
Maximum cumulative dose reached	**C**
Progressive disease (radiologically established)	**D**
Progressive disease (clinical progression)	**E**
Clinical deterioration necessitating stopping further treatment	**F**
Absent overall risk-benefit of continued treatment (patient´s or family´s decision)	**G**
Absent overall risk-benefit of continued treatment (physician´s decision)	**H**
Treatment completed as per planning (received all planned cycles of the treatment)	**I**
Other	**J**

IF E25K, E25L E25M, E25N OR E25 O = nal-IRI or Onivid or MM-398
AND E36=A OR D OR E THEN Display Adverse Event Forms

[SHOW IF E21=1] SECTION 3 UP TO PAGE 35

ADJUVANT TREATMENT

E37. Start date of treatment (DD/MM/YYYY)

|_|_| |_|_| |_|_|_|_|

[Min E19_3; Max E6]

E38. End date of the treatment (DD/MM/YYYY)

|_|_| |_|_| |_|_|_|_|

[Min>=E37; Max E6]

E39. Was this adjuvant treatment given in the context of a Clinical Trial?

	Tick only one
Yes	○ 1
No	○ 2

E40. What adjuvant treatment did the patient receive? Please select if one of the regimen below was used

INSERT SAME TABLE E24	*Tick only one*

[SHOW IF E40=21]

E41. Please select what chemotherapeutic treatment the patient received as adjuvant therapy.

Select as many agents as it applies. If you only select one compound, we understand that you used it in monotherapy.

INSERT SAME TABLE E25	

Confirmation of regimen (selected in E24)

[SHOW IF E40=1 to 10]

E41_0	**Please confirm the regimen** **INSERT SAME TABLE E24_1**	**Absolute dose given in the first cycle**

[SHOW IF E21=1]

FOR PROGRAMMING PURPOSES, EACH REGIMEN IN E40 IS SPLIT INTO E41 VARIABLES.

E42. INITIAL DOSE AND FREQUENCY REGIMEN

Same table as E26 (change variables)	[[Only one unit per dose]	Frequency	Other Frequency (not listed) Specify	Absolute dose given in the first cycle
Paclitaxel SHOW IF E41=A]	Dose: _____ □ mg / m2 If other unit used, please tick: □ mg □ mg / Kg	Frequency: [Show dropdown: once weekly / every 3 weeks]	Open-end	Total mg _____ mg
Etc.				
Etc.				

[SHOW IF E21=1]

E43. How many cycles did the patient receive? ⌊_⌋⌊_⌋

[MIN 1 -MAX 10]

E44. Was the initial regimen modified (doses, delays, compound stopped)?

	Tick only one
Yes, it was modified	1
No, it was maintained all through the entire adjuvant treatment	2

[SHOW IF E44=1]

E45. DOSING / TREATMENT CHANGES

Doctor, you mentioned that there were modifications in the therapy please indicate what product and in which cycle there were changes:

SHOW AS MANY COLUMNS AS E43

Tick all that apply– At least one tick

SHOW PRODUCTS SELECTED (E40 /) E41	Cycle 1	Cycle 2	Cycle 2	Cycle 3	Etc.		
Product 1	AA	BA	CA	DA			
Product 2	AB	BB	CB	DB			
Product 3	AC	BC	CC	DC			
Product 4	AD	BD	CD	DD			
Etc.							

[NEXT SCREEN]

E46. Doctor, you mentioned that there were modifications in the therapy please indicate for each product and cycle the modifications.

RECALL E45	Tick all that apply	Specify	Total absolute dose for this cycle
Eg. IF AA TICKED **Product 1, cycle 1**	Dose delayed ○ **A**	By how many days the dose was delayed_____	
	Dose modified ○ **B**	**RECALL PREVIOUS DOSE** Enter the new dose_____	_____ Total mg Tick box if other dosing unit: _____**INSERT OPEN END**
	Product stopped ○ **C**		
Etc.			

[SHOW IF E46=C] FOR EACH PRODUCT SELECTED

E47. Why was one or more compounds stopped?

	Tick all that apply
Dose-limiting toxicity / Side effects	**A**
Prevention of future toxicity / Side effects (not yet dose-limiting before) per physician´s guidance	**B**
Prevention of future toxicity / Side effects (not yet dose-limiting before) per patient's or family's decision	**C**
Maximum cumulative dose reached	**D**
Logistical reasons (hospital planning related)	**E**
Logistical reasons (patient´s or family´s request)	**F**
No anti-tumour value of continued treatment per physician´s guidance	**G**
No overall value of continued treatment (overall risk-benefit) per physician´s guidance	**I**
No overall value of continued treatment (overall risk-benefit) per patient's/family's decision	**J**
Other	**K**

IF E41K, E41L E41M, E41N OR E41 O = nal-IRI or Onivid or MM-398 AND E47=A THEN Display Adverse Event Forms

[SHOW IF E46=A] FOR EACH PRODUCT SELECTED

E48. Why was dose delayed?

	Tick all that apply
Dose-limiting toxicity / Side effects	**A**
Prevention of future toxicity / Side effects (not yet dose-limiting before) per physician´s guidance	**B**
Prevention of future toxicity / Side effects (not yet dose-limiting before) per patient's or family's decision	**C**
Logistical reasons (hospital planning related)	**E**
Logistical reasons (patient´s or family´s request)	**F**
Other	**K**

IF E41K, E41L E41M, E41N OR E41 O = nal-IRI or Onivid or MM-398 AND E48=A, THEN Display Adverse Event Forms

[SHOW IF E46=B FOR EACH PRODUCT SELECTED

E49. Why were doses modified?

	Tick all that apply
Dose-limiting toxicity / Side effects	**A**
Prevention of future toxicity / Side effects (not yet dose-limiting before) per physician´s guidance	**B**
Prevention of future toxicity / Side effects (not yet dose-limiting before) per patient's or family's decision	**C**
No overall value of continued full treatment (overall risk-benefit) per physician´s guidance	**I**
No overall value of continued full treatment (overall risk-benefit) per patient's/family's decision	**J**
Other	**K**

IF E41K, E41L E41M, E41N OR E41 O = nal-IRI or Onivid or MM-398 AND E49=A, THEN Display Adverse Event Forms

[SHOW IF E21=1]

E50. What was the outcome of this treatment?

	Tick only one
Local recurrence	○ **1**
Metastatic disease	○ **2**
No sign of local recurrence/metastatic disease	○ **3**

E51. Why was the adjuvant treatment stopped?

	Tick all that apply
Toxicity / Side effects	**A**
Prevention of future toxicity / side-effects	**B**
Maximum cumulative dose reached	**C**
Progressive disease (radiologically established)	**D**
Progressive disease (clinical progression)	**E**
Clinical deterioration necessitating stopping further treatment	**F**
Absent overall risk-benefit of continued treatment (patient´s or family´s decision)	**G**
Absent overall risk-benefit of continued treatment (physician´s decision)	**H**
Treatment completed as per planning (received all planned cycles of the treatment)	**I**
Other	**J**

IF E41K, E41L E41M, E41N OR E41 O = nal-IRI or Onivid or MM-398 AND E48=A, DE, E THEN Display Adverse Event Forms

[SHOW IF E18=3] SECTION 4 UP TO PAGE 42

TREATMENT FOR LOCALLY ADVANCED UNRESECTABLE (AT THE TIME OF DIAGNOSIS) DISEASE

[SHOW IF E18=3]

E52. Start date of treatment (DD/MM/YYYY)

|_|_| |_|_| |_|_|_|_|

[Min E5 ; Max E6]

[SHOW IF E18=3]

E53. End date of the treatment (DD/MM/YYYY)

|_|_| |_|_| |_|_|_|_|

[Min >E52; Max E6]

[SHOW IF E18=3]

E54. Was this treatment given in the context of a Clinical Trial?

	Tick only one
Yes	○ 1
No	○ 2

[SHOW IF E18=3]

E55. What chemotherapeutic treatment did the patient receive? Please select if one of the regimen below was used

INSERT SAME TABLE E24	

[SHOW IF E55=21]

E56. Please select what chemotherapeutic treatment the patient received.
Select as many agents as it applies. If you only select one compound, we understand that you used it in monotherapy.

SAME TABLE AS E25	*Tick all that apply*
	A

[SHOW IF E55=1 to 10]

Confirmation of regimen (selected in E55)

E55_0	Please confirm the regimen INSERT SAME TABLE AS E24_0	Absolute dose given in the first cycle

[SHOW IF E18=3]

FOR PROGRAMMING PURPOSES, EACH REGIMEN IN E55 IS SPLIT INTO E56 VARIABLES.

E57. INITIAL DOSE AND FREQUENCY REGIMEN

Same table as E26 (change variables)	[[Only one unit per dose]	Frequency	Other Frequency (not listed) Specify	Absolute dose given in the first cycle
Paclitaxel SHOW IF E56=A]	Dose: _____ □ mg / m2 If other unit used, please tick: □ mg □ mg / Kg	Frequency: [Show dropdown: once weekly / every 3 weeks]	Open-end	Total mg _____ mg
Etc.				
Etc.				

[SHOW IF E18=3]

E58. How many cycles did the patient receive? ⌊__⌋⌊__⌋

[MIN 1 -MAX 10]

[SHOW IF E18=3]

E59. Was the initial regimen modified (doses, delays, compound stopped)?

	Tick only one
Yes, it was modified	1
No, it was maintained all through the cycles	2

[SHOW IF E59=1]

E60. DOSING CHANGES

Doctor, you mentioned that there were modifications in the therapy please indicate what product and in which cycle there were changes:

SHOW AS MANY COLUMNS AS E58
Tick all that apply– At least one tick

SHOW PRODUCTS SELECTED (E55/) E_56	Cycle 1	Cycle 2	Cycle 2	Cycle 3	Etc.		
Product 1	AA	BA	CA	DA			
Product 2	AB	BB	CB	DB			
Product 3	AC	BC	CC	DC			
Product 4	AD	BD	CD	DD			
Etc.							

[SHOW IF E59=1]
E61. Doctor, you mentioned that there were modifications in the therapy please indicate for each product and cycle the modifications.

RECALL E60	Tick all that apply	Specify	Total absolute dose for this cycle
Eg. IF AA TICKED **Product 1, cycle 1**	Dose delayed ○ **A**	By how many days the dose was delayed_____	
	Dose modified ○ **B**	**RECALL PREVIOUS DOSE** Enter the new dose_____	_____ Total mg Tick box if other dosing unit: _____**INSERT OPEN END**
	Product stopped ○ **C**		
Etc.			

[SHOW IF E61=C] FOR EACH PRODUCT SELECTED

E62. Why was one or more compounds stopped?

	Tick all that apply
Dose-limiting toxicity / Side effects	**A**
Prevention of future toxicity / Side effects (not yet dose-limiting before) per physician´s guidance	**B**
Prevention of future toxicity / Side effects (not yet dose-limiting before) per patient's or family's decision	**C**
Maximum cumulative dose reached	**D**
Logistical reasons (hospital planning related)	**E**
Logistical reasons (patient´s or family´s request)	**F**
No anti-tumour value of continued treatment per physician´s guidance	**G**
No overall value of continued treatment (overall risk-benefit) per physician´s guidance	**H**
No overall value of continued treatment (overall risk-benefit) per patient's/family's decision	**I**
Other	**J**

IF E56K, E56L E56M, E56N OR E56 O = nal-IRI or Onivid or MM-398 AND E62=A THEN Display Adverse Event Forms

[SHOW IF E61=A] FOR EACH PRODUCT SELECTED

E63. Why was dose delayed?

	Tick all that apply
Dose-limiting toxicity / Side effects	**A**
Prevention of future toxicity / Side effects (not yet dose-limiting before) per physician´s guidance	**B**
Prevention of future toxicity / Side effects (not yet dose-limiting before) per patient's or family's decision	**C**
Logistical reasons (hospital planning related)	**D**
Logistical reasons (patient´s or family´s request)	**E**
Other	**F**

IF E56K, E56L E56M, E56N OR E56 O = nal-IRI or Onivid or MM-398 AND E63=A THEN Display Adverse Event Forms

[SHOW IF E61=B] FOR EACH PRODUCT SELECTED

E64. Why were doses modified?

	Tick all that apply
Dose-limiting toxicity / Side effects	**A**
Prevention of future toxicity / Side effects (not yet dose-limiting before) per physician´s guidance	**B**
Prevention of future toxicity / Side effects (not yet dose-limiting before) per patient's or family's decision	**C**
No overall value of continued full treatment (overall risk-benefit) per physician´s guidance	**D**
No overall value of continued full treatment (overall risk-benefit) per patient's/family's decision	**E**
Other	**F**

IF E56K, E56L E56M, E56N OR E56 O = nal-IRI or Onivid or MM-398 AND E64=A, THEN Display Adverse Event Forms

[SHOW if E18=3]

E65. What was the best response of this treatment?

	Tick only one
Complete response	○ **1**
Partial Response	○ **2**
Stable disease	○ 3
Progressive disease	○ 4

[SHOW if E18=3]

E66. Why was the treatment for locally advanced unresectable tumour stopped?

	Tick all that apply
Toxicity / Side effects	**A**
Prevention of future toxicity / side-effects	**B**
Maximum cumulative dose reached	**C**
Progressive disease (radiologically established)	**D**
Progressive disease (clinical progression)	**E**
Clinical deterioration necessitating stopping further treatment	**F**
Absent overall risk-benefit of continued treatment (patient´s or family´s decision)	**G**
Absent overall risk-benefit of continued treatment (physician´s decision)	**H**
Treatment completed as per planning (received all planned cycles of the treatment)	**I**
Other	**J**

IF E56K, E56L E56M, E56N OR E56 O = nal-IRI or Onivid or MM-398
AND E66=A, D, E THEN Display Adverse Event Forms

[SHOW ALL] SECTION 5 UP TO PAGE 45

Metastatic setting

E67. Location of metastases at first diagnosis of metastatic disease

		Tick all that apply
A	Peritoneum	☐ **[E67A]**
B	Liver	☐ **[E67B]**
C	Lung and pleura	☐ **[E67C]**
D	Bone	☐ **[E67D]**
E	Brain	☐ **[E67E]**
F	Adrenal glands	☐ **[E67F]**
G	Other	☐ **[E67G]**

[SHOW IF E16= 1 TO 6 OR E16=8]

E68. Performance status at diagnosis of metastatic disease

ECOG Grade	Karnofsky Grade	Tick only one
0	100	○ **1**
1	80-90	○ **2**
2	60-70	○ **3**
3	40-50	○ **4**
4	10-30	○ **5**
Unknown		○ **6**

For details on the ECOG and Karnofsky Grade, please click here. [INSERT LINK – APPENDIX 1]

[SHOW IF E16= 1 TO 6 OR E16=8]

E69. Please indicate level at first diagnosis of metastatic disease

			Tick if not performed	To be programmed	
				MIN	**MAX**
1	CA19-9	_____U/ml		0	5000
2	Albumin	_____ g/l		15 g/l	80 g/l
3	Bilirubin	_____ IU/L _____µmol/		0.1 IU/l 5 µmol /l	30,000 IU/L 700 µmol/l

[IF OUTSIDE RANGES ASK] **Can you please confirm this value?**

YES / NO **[IF YES GO TO NEXT QUESTION, IF NO GO BACK TO E69]**

[SHOW ALL]

E70. Comorbidities at moment of diagnosis of metastatic disease

		Tick all that apply
A	Obesity	☐ **[E70A]**
B	Hypertension	☐ **[E70B]**
C	Diabetes mellitus	☐ **[E70C]**
D	Former smoker	☐ **[E70D]**
E	Current smoker	☐ **[E70E]**
F	Depression	☐ **[E70F]**
G	Chronic Pulmonary Disease	☐ **[E70G]**
H	History of myocardial infarction	☐ **[E70H]**
I	Hypercalcemia	☐ **[E70I]**
	Other	
	None	

[SHOW ALL] SECTION 6 UP TO PAGE 53

First line metastatic treatment

[SHOW ALL]

E71. Start date of the 1st line metastatic treatment (DD/MM/YYYY) |__|__| |__|__| |__|__|__|__|

[Min => E6 ; Max 1/10/2015]

[SHOW ALL]

E72. End date of the 1st line metastatic treatment (DD/MM/YYYY) |__|__| |__|__| |__|__|__|__|

[Min >E71 ; Max 1/10/2015]

[SHOW ALL]

E73. Was this treatment given in the context of a Clinical Trial?

	Tick only one
Yes	○ 1
No	○ 2

[SHOW ALL]

E74. What treatment did the patient receive in 1ST Line? Please select if one of the regimen below was used

INSERT SAME TABLE E24	*Tick only one*

[SHOW IF E74=21]

E75. Please select what chemotherapeutic treatment the patient received in 1ST line.

Select as many agents as it applies. If you only select one compound, we understand that you used it in monotherapy.

INSERT SAME TABLE E25	

[SHOW IF E74=1 to 10]

Confirmation of regimen (selected in E74)

E74_0	**Please confirm the regimen** **INSERT SAME TABLE E24_1**	**Absolute dose given in the first cycle**

[SHOW ALL]

FOR PROGRAMMING PURPOSES, EACH REGIMEN IN E74 IS SPLIT INTO E75 VARIABLES.

E76. INITIAL DOSE AND FREQUENCY REGIMEN

Same table as E26 (change variables)	[[Only one unit per dose]	Frequency	Other Frequency (not listed) Specify	Absolute dose given in the first cycle
Paclitaxel SHOW IF E75=A]	Dose: _____ □ mg / m2 If other unit used, please tick: □ mg □ mg / Kg	Frequency: [Show dropdown: once weekly / every 3 weeks]	Open-end	Total mg _____ mg
Etc.				
Etc.				

[SHOW ALL]

E77. How many cycles did the patient receive?

[MIN 1-MAX 10] ☐☐

[SHOW ALL]

E78. Was the initial regimen modified (doses, delays, compound stopped?

	TICK ONLY ONE
YES	1
NO, it was maintained all through the entire 1st line treatment	2

[SHOW IF E78=1]

E79. DOSING CHANGES

Doctor, you mentioned that there were modifications in the therapy please indicate what product and in which cycle there were changes:

SHOW AS MANY COLUMNS AS E77
Tick all that apply– At least one tick

SHOW PRODUCTS SELECTED (E74 / E75)	Cycle 1	Cycle 2	Cycle 2	Cycle 3	Etc.		
Product 1	AA	BA	CA	DA			
Product 2	AB	BB	CB	DB			
Product 3	AC	BC	CC	DC			
Product 4	AD	BD	CD	DD			
Etc.							

[NEXT SCREEN]

E80. Doctor, you mentioned that there were modifications in the therapy please indicate for each product and cycle the modifications.

RECALL E79	Tick all that apply	Specify	Total absolute dose for this cycle
Eg. IF AA TICKED **Product 1, cycle 1**	Dose delayed ○ **A**	By how many days the dose was delayed_____	
	Dose modified ○ **B**	RECALL PREVIOUS DOSE Enter the new dose_____	_____ Total mg Tick box if other dosing unit: _____INSERT OPEN END
	Product stopped ○ **C**		
Etc.			

[SHOW IF E79=C] FOR EACH PRODUCT SELECTED

E81. Why was one or more compounds stopped?

	Tick all that apply
Dose-limiting toxicity / Side effects	**A**
Prevention of future toxicity / Side effects (not yet dose-limiting before) per physician´s guidance	**B**
Prevention of future toxicity / Side effects (not yet dose-limiting before) per patient's or family's decision	**C**
Maximum cumulative dose reached	**D**
Logistical reasons (hospital planning related)	**E**
Logistical reasons (patient´s or family´s request)	**F**
No anti-tumour value of continued treatment per physician´s guidance	**G**
No overall value of continued treatment (overall risk-benefit) per physician´s guidance	**H**
No overall value of continued treatment (overall risk-benefit) per patient's/family's decision	**I**
Other	**J**

IF E75K, E75L E75M, E75N OR E75 O = nal-IRI or Onivid or MM-398 AND E81=A THEN Display Adverse Event Forms

[SHOW IF E79=A] FOR EACH PRODUCT SELECTED

E82. Why was dose delayed?

	Tick all that apply
Dose-limiting toxicity / Side effects	**A**
Prevention of future toxicity / Side effects (not yet dose-limiting before) per physician´s guidance	**B**
Prevention of future toxicity / Side effects (not yet dose-limiting before) per patient's or family's decision	**C**
Logistical reasons (hospital planning related)	**D**
Logistical reasons (patient´s or family´s request)	**E**
Other	**F**

IF E75K, E75L E75M, E75N OR E75 O = nal-IRI or Onivid or MM-398 AND E82=A, THEN Display Adverse Event Forms

[SHOW IF E79=B] FOR EACH PRODUCT SELECTED

E83. Why were doses modified?

	Tick all that apply
Dose-limiting toxicity / Side effects	**A**
Prevention of future toxicity / Side effects (not yet dose-limiting before) per physician´s guidance	**B**
Prevention of future toxicity / Side effects (not yet dose-limiting before) per patient's or family's decision	**C**
No overall value of continued full treatment (overall risk-benefit) per physician´s guidance	**D**
No overall value of continued full treatment (overall risk-benefit) per patient's/family's decision	**E**
Other	**F**

IF E75K, E75L E75M, E75N OR E75 O = nal-IRI or Onivid or MM-398 AND E83=A THEN Display Adverse Event Forms

[SHOW ALL]

E84. What was the performance status at start of 1st line

ECOG Grade	Karnofsky Grade	Tick only one
0	100	○ 1
1	80-90	○ 2
2	60-70	○ 3
3	40-50	○ 4
4	10-30	○ 5
Unknown		○ 6

For details on the ECOG and Karnofsky Grade, please click here. [INSERT LINK – APPENDIX 1]

[SHOW ALL]

E85. Please indicate level at start of 1st line metastatic treatment

			Tick if not performed	To be programmed MIN	To be programmed MAX
1	CA19-9	_____U/ml		0	5000
2	Albumin	_____ g/l		15 g/l	80 g/l
3	Bilirubin	_____ IU/L _____µmol/		0.1 IU/l 5 µmol /l	30,000 IU/L 700 µmol/l

[IF OUTSIDE RANGES] Can you please confirm this value?

YES / NO [IF YES GO TO NEXT QUESTION, IF NO GO BACK TO E85

[SHOW ALL]

E86. Best radiological response to treatment

	Tick only one
Complete response	○ 1
Partial response	○ 2
Stable disease	○ 3
Progressive disease	○ 4

[SHOW ALL]

E87. Did the patient progress?

	Tick only one
YES	○ 1
NO	○ 2

IF E75K, E75L E75M, E75N OR E75 O = nal-IRI or Onivid or MM-398 AND E87=1 THEN Display Adverse Event Forms

[SHOW IF E87=1]

E88. When was progression documented? (DD/MM/YYYY) ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋

[Min => E71 ; Max today]

[SHOW IF E87=1]

E89. How was progression documented?

	Tick only one
Radiologically	○ 1
Clinically	○ 2
Both	○ 3

[SHOW ALL]

E90. Why was 1st line treatment stopped?

	Tick all that apply
Toxicity / Side effects	**A**
Prevention of future toxicity / side-effects	**B**
Maximum cumulative dose reached	**C**
Progressive disease (radiologically established)	**D**
Progressive disease (clinical progression)	**E**
Clinical deterioration necessitating stopping further treatment	**F**
Absent overall risk-benefit of continued treatment (patient´s or family´s decision)	**G**
Absent overall risk-benefit of continued treatment (physician´s decision)	**H**
Treatment completed as per planning (received all planned cycles of the treatment)	**I**
Other	**J**
Death **[HIDE IF E3=1]**	H

IF E75K, E75L E75M, E75N OR E75 O = nal-IRI or Onivid or MM-398 AND E90=A, D, E,H THEN Display Adverse Event Forms

[SHOW IF E3A>=3 OR E3B>=4]
SECTION 7 UP TO PAGE 62

Second line metastatic treatment

E91. Start date of the 2nd line metastatic treatment (DD/MM/YYYY) |_|_| |_|_| |_|_|_|_|

[Min => E72 ; Max today]

[SHOW IF E3A>=4 OR E3B>=5]

E92. End date of the 2nd line metastatic treatment (DD/MM/YYYY) |_|_| |_|_| |_|_|_|_|

[Min >E91 ; Max today]

[SHOW IF E3A>=3 OR E3B>=4]

E93. Was this treatment given in the context of a Clinical Trial?

	Tick only one
Yes	○ **1**
No	○ **2**

[SHOW IF E3A>=3 OR E3B>=4]

E94. What treatment did the patient receive in 2nd Line? Please select if one of the regimen below was used

INSERT SAME TABLE E24	*Tick only one*

[SHOW IF E94=21]

E95. Please select what chemotherapeutic treatment the patient received in 2nd line.

Select as many agents as it applies. If you only select one compound, we understand that you used it in monotherapy.

INSERT SAME TABLE E25	

[SHOW IF E94=1 to 10]

Confirmation of regimen (selected in E94)

E94_0	**Please confirm the regimen** **INSERT SAME TABLE E24_1**	**Absolute dose given in the first cycle**

[SHOW IF E3A>=3 OR E3B>=4]
FOR PROGRAMMING PURPOSES, EACH REGIMEN IN E94IS SPLIT INTO E95 VARIABLES.

E96. INITIAL DOSE AND FREQUENCY REGIMEN

Same table as E26 (change variables)	[[Only one unit per dose]	Frequency	Other Frequency (not listed) Specify	Absolute dose given in the first cycle
Paclitaxel SHOW IF E95=A]	Dose: _____ □ mg / m2 If other unit used, please tick: □ mg □ mg / Kg	Frequency: [Show dropdown: once weekly / every 3 weeks]	Open-end	Total mg _____ mg
Etc.				
Etc.				

[SHOW IF E3A>=3 OR E3B>=4]
E97. How many cycles did the patient receive?
[MIN 1 -MAX 10]

[SHOW IF E3A>=3 OR E3B>=4]
E98. Was the initial regimen maintained all through the entire 2nd line or was it modified (doses, delays, compound stopped)?

	TICK ONLY ONE
Yes, it was modified	1
No, it was maintained all through the cycles	2

[SHOW IF E98=1]:

E99. DOSING CHANGES

Doctor, you mentioned that there were modifications in the therapy please indicate what product and in which cycle there were changes:

SHOW AS MANY COLUMNS AS E97

Tick all that apply– At least one tick

SHOW PRODUCTS SELECTED (E94/ E95	Cycle 1	Cycle 2	Cycle 2	Cycle 3	Etc.		
Product 1	AA	BA	CA	DA			
Product 2	AB	BB	CB	DB			
Product 3	AC	BC	CC	DC			
Product 4	AD	BD	CD	DD			
Etc.							

NEXT SCREEN]

E100. Doctor, you mentioned that there were modifications in the therapy please indicate for each product and cycle the modifications.

RECALL E99	Tick all that apply	Specify	Total absolute dose for this cycle
Eg. IF AA TICKED **Product 1, cycle 1**	Dose delayed ○ **A**	By how many days the dose was delayed_____	
	Dose modified ○ **B**	RECALL PREVIOUS DOSE Enter the new dose_____	_____ Total mg Tick box if other dosing unit: _____INSERT OPEN END
	Product stopped ○ **C**		
Etc.			

[SHOW IF E100=C] FOR EACH PRODUCT SELECTED

E101. Why was one or more compounds stopped?

	Tick all that apply
Dose-limiting toxicity / Side effects	**A**
Prevention of future toxicity / Side effects (not yet dose-limiting before) per physician´s guidance	**B**
Prevention of future toxicity / Side effects (not yet dose-limiting before) per patient's or family's decision	**C**
Maximum cumulative dose reached	**D**
Logistical reasons (hospital planning related)	**E**
Logistical reasons (patient´s or family´s request)	**F**
No anti-tumour value of continued treatment per physician´s guidance	**G**
No overall value of continued treatment (overall risk-benefit) per physician´s guidance	**H**
No overall value of continued treatment (overall risk-benefit) per patient's/family's decision	**I**
Other	**J**

IF E95=D AND E101=A, THEN Display Adverse Event Forms

[SHOW IF E100=A] FOR EACH PRODUCT SELECTED

E102. Why was dose delayed?

	Tick all that apply
Dose-limiting toxicity / Side effects	**A**
Prevention of future toxicity / Side effects (not yet dose-limiting before) per physician´s guidance	**B**
Prevention of future toxicity / Side effects (not yet dose-limiting before) per patient's or family's decision	**C**
Logistical reasons (hospital planning related)	**D**
Logistical reasons (patient´s or family´s request)	**E**
Other	**F**

IF E95K, E95L E95M, E95N OR E95 O = nal-IRI or Onivid or MM-398 AND E102=A, THEN Display Adverse Event Forms

[SHOW IF E100=B] FOR EACH PRODUCT SELECTED

E103. Why were doses reduced?

	Tick all that apply
Dose-limiting toxicity / Side effects	**A**
Prevention of future toxicity / Side effects (not yet dose-limiting before) per physician´s guidance	**B**
Prevention of future toxicity / Side effects (not yet dose-limiting before) per patient's or family's decision	**C**
No overall value of continued full treatment (overall risk-benefit) per physician´s guidance	**D**
No overall value of continued full treatment (overall risk-benefit) per patient's/family's decision	**E**
Other	**F**

IF E95K, E95L E95M, E95N OR E95 O = nal-IRI or Onivid or MM-398 AND E103=A, THEN Display Adverse Event Forms

[SHOW IF E3A>=3 OR E3B>=4]

E104. What was the performance status at start of 2nd line

ECOG Grade	Karnofsky Grade	Tick only one
0	100	○ 1
1	80-90	○ 2
2	60-70	○ 3
3	40-50	○ 4
4	10-30	○ 5
Unknown		○ 6

For details on the ECOG and Karnofsky Grade, please click here. [INSERT LINK – APPENDIX 1]

[SHOW IF E3A>=3 OR E3B>=4]

E105. Please indicate level at start of 2nd line metastatic treatment

			Tick if not performed	To be programmed MIN	To be programmed MAX
1	CA19-9	_____U/ml		0	5000
2	Albumin	_____ g/l		15 g/l	80 g/l
3	Bilirubin	_____ IU/L _____µmol/		0.1 IU/l 5 µmol /l	30,000 IU/L 700 µmol/l

[IF OUTSIDE RANGES ASK] Can you please confirm this value?

YES / NO [IF YES GO TO NEXT QUESTION, IF NO GO BACK TO E104]

[SHOW IF E3A>=3 OR E3B>=4]

E106. Best radiological response to treatment

	Tick only one
Complete response	○ 1
Partial response	○ 2
Stable disease	○ 3
Progressive disease	○ 4

[SHOW IF E3A>=3 OR E3B>=4]

E107. Did the patient progress?

	Tick only one
YES	○ 1
NO	○ 2

IF E95K, E95L E95M, E95N OR E95 O = nal-IRI or Onivid or MM-398 AND E107=1, THEN Display Adverse Event Forms

[SHOW IF E107=1]

E108. When was progression documented? (DD/MM/YYYY)

|_|_| |_|_| |_|_|_|_|

[Min => E91 ; Max 1/10/2015]

[SHOW IF E107=1]

E109. How was progression documented?

	Tick only one
Radiologically	○ **1**
Clinically	○ **2**
Both	○ **3**

[SHOW IF E3A>=3 OR E3B>=4]

E110. Why was 2nd line treatment stopped?

	Tick all that apply
Toxicity / Side effects	**A**
Prevention of future toxicity / side-effects	**B**
Maximum cumulative dose reached	**C**
Progressive disease (radiologically established)	**D**
Progressive disease (clinical progression)	**E**
Clinical deterioration necessitating stopping further treatment	**F**
Absent overall risk-benefit of continued treatment (patient´s or family´s decision)	**G**
Absent overall risk-benefit of continued treatment (physician´s decision)	**H**
Treatment completed as per planning (received all planned cycles of the treatment)	**I**
Other	**J**
Death **[HIDE IF E3=1]**	**K**

IF E95K, E95L E95M, E95N OR E95 O = nal-IRI or Onivid or MM-398 AND E110=A, D, E, K THEN Display Adverse Event Forms

[SHOW IF E3A>=6 OR E3>=7] SECTION 8 UP TO PAGE 70

Third line metastatic treatment

E111.Start date of the 3rd line metastatic treatment (DD/MM/YYYY) |__|__|__|__|__|__|__|__|

[Min E92 ; Max today]

[SHOW IF E3A>=7 OR E3B>=8]

E112.End date of the 3rd line metastatic treatment (DD/MM/YYYY) |__|__|__|__|__|__|__|__|

[Min E111 ; Max today]

[SHOW IF E3A>=6 OR E3>=7]

E113. Was this treatment given in the context of a Clinical Trial?

	Tick only one
Yes	○ **1**
No	○ **2**

[SHOW IF E3A>=6 OR E3>=7]

E114. What treatment did the patient receive in 3rd line? Please select if one of the regimen below was used

INSERT SAME TABLE E24	*Tick only one*

[SHOW IF E114=21]

E115. Please select what chemotherapeutic treatment the patient received in 3rd line.

Select as many agents as it applies. If you only select one compound, we understand that you used it in monotherapy.

INSERT SAME TABLE E25	

[SHOW IF E114=1 to 10]

Confirmation of regimen (selected in E114)

E114_0	**Please confirm the regimen** **INSERT SAME TABLE E24_1**	**Absolute dose given in the first cycle**

SHOW IF E3A>=6 OR E3>=7
FOR PROGRAMMING PURPOSES, EACH REGIMEN IN E114 IS SPLIT INTO E115 VARIABLES.

E116. INITIAL DOSE AND FREQUENCY REGIMEN

Same table as E26 (change variables)	[[Only one unit per dose]	Frequency	Other Frequency (not listed) Specify	Absolute dose given in the first cycle
Paclitaxel SHOW IF E114=A]	Dose: _____ ☐ mg / m2 If other unit used, please tick: ☐ mg ☐ mg / Kg	Frequency: [Show dropdown: once weekly / every 3 weeks]	Open-end	Total mg _____ mg
Etc.				
Etc.				

[SHOW IF E3A>=6 OR E3>=7]

E117. How many cycles did the patient receive? ☐☐

[MIN 1-MAX 10]

[SHOW IF E3A>=6 OR E3>=7]

E118. Was the initial regimen modified (doses, delays, compound stopped)?

	Tick only one
Yes, it was modified	1
No, it was maintained all through the cycles	2

[SHOW IF E118=1]:

E119. DOSING CHANGES

Doctor, you mentioned that there were modifications in the therapy please indicate what product and in which cycle there were changes:

SHOW AS MANY COLUMNS AS E117

Tick all that apply– At least one tick

SHOW PRODUCTS SELECTED (E114/) E115	Cycle 1	Cycle 2	Cycle 2	Cycle 3	Etc.		
Product 1	AA	BA	CA	DA			
Product 2	AB	BB	CB	DB			
Product 3	AC	BC	CC	DC			
Product 4	AD	BD	CD	DD			
Etc.							

NEXT SCREEN]

E120. Doctor, you mentioned that there were modifications in the therapy please indicate for each product and cycle the modifications.

RECALL E119	Tick all that apply	Specify	Total absolute dose for this cycle
Eg. IF AA TICKED **Product 1, cycle 1**	Dose delayed ○ **A**	By how many days the dose was delayed_____	
	Dose modified ○ **B**	RECALL PREVIOUS DOSE Enter the new dose_____	_____ Total mg Tick box if other dosing unit: _____INSERT OPEN END
	Product stopped ○ **C**		
Etc.			

[SHOW IF E120=C] FOR EACH PRODUCT SELECTED

E121. Why was one or more compounds stopped?

	Tick all that apply
Dose-limiting toxicity / Side effects	**A**
Prevention of future toxicity / Side effects (not yet dose-limiting before) per physician´s guidance	**B**
Prevention of future toxicity / Side effects (not yet dose-limiting before) per patient's or family's decision	**C**
Maximum cumulative dose reached	**D**
Logistical reasons (hospital planning related)	**E**
Logistical reasons (patient´s or family´s request)	**F**
No anti-tumour value of continued treatment per physician´s guidance	**G**
No overall value of continued treatment (overall risk-benefit) per physician´s guidance	**H**
No overall value of continued treatment (overall risk-benefit) per patient's/family's decision	**I**
Other	**J**

IF E115K, E115L E115M, E115N OR E115 O = nal-IRI or Onivid or MM-398 AND E121=A, THEN Display Adverse Event Forms

[SHOW IF E120=A]

E122. Why was dose delayed?

	Tick all that apply
Dose-limiting toxicity / Side effects	**A**
Prevention of future toxicity / Side effects (not yet dose-limiting before) per physician´s guidance	**B**
Prevention of future toxicity / Side effects (not yet dose-limiting before) per patient's or family's decision	**C**
Logistical reasons (hospital planning related)	**D**
Logistical reasons (patient´s or family´s request)	**E**
Other	**F**

IF E115K, E115L E115M, E115N OR E115 O = nal-IRI or Onivid or MM-398 AND E122=A, THEN Display Adverse Event Forms
[SHOW IF E120=B]

E123. Why were doses reduced?

	Tick all that apply
Dose-limiting toxicity / Side effects	**A**
Prevention of future toxicity / Side effects (not yet dose-limiting before) per physician´s guidance	**B**
Prevention of future toxicity / Side effects (not yet dose-limiting before) per patient's or family's decision	**C**
No overall value of continued full treatment (overall risk-benefit) per physician´s guidance	**D**
No overall value of continued full treatment (overall risk-benefit) per patient's/family's decision	**E**
Other	**F**

IF E115K, E115L E115M, E115N OR E115 O = nal-IRI or Onivid or MM-398 AND E123=A, THEN Display Adverse Event Forms

[SHOW IF E3A>=6 OR E3>=7]

E124. What was the performance status at start of 3rd line

ECOG Grade	Karnofsky Grade	Tick only one
0	100	○ **1**
1	80-90	○ **2**
2	60-70	○ **3**
3	40-50	○ **4**
4	10-30	○ **5**
Unknown		○ **6**

For details on the ECOG and Karnofsky Grade, please click here. [INSERT LINK – APPENDIX 1]

[SHOW IF E3A>=6 OR E3>=7]

E125. Please indicate level at start of 3rd line metastatic treatment

				To be programmed	
			Tick if not performed	**MIN**	**MAX**
1	CA19-9	_____U/ml		0	5000
2	Albumin	_____ g/l		15 g/l	80 g/l
3	Bilirubin	_____ IU/L _____µmol/		0.1 IU/l 5 µmol /l	30,000 IU/L 700 µmol/l

[IF OUTSIDE ranges ASK] Can you please confirm this value?

YES / NO [IF YES GO TO NEXT QUESTION, IF NO GO BACK TO E125]

[SHOW IF E3A>=6 OR E3>=7]

E126. Best radiological response to treatment

	Tick only one
Complete response	○ 1
Partial response	○ 2
Stable disease	○ 3
Progressive disease	○ 4

[SHOW IF E3A>=6 OR E3>=7]

E127. Did the patient progress?

	Tick only one
YES	○ 1
NO	○ 2

IF E115K, E115L E115M, E115N OR E115 O = nal-IRI or Onivid or MM-398 AND E127=1, THEN Display Adverse Event Forms

[SHOW IF E127=1]

E128. When was progression documented? (DD/MM/YYYY)

|_|_| |_|_| |_|_|_|_|

[Min => E111 ; Max 1/10/2015]

[SHOW IF E127=1]

E129. How was progression documented?

	Tick only one
Radiologically	○ **1**
Clinically	○ **2**
Both	○ **3**

[SHOW IF E3A>=6 OR E3>=7]

E130. Why was 3rd line treatment stopped?

	Tick all that apply
Toxicity / Side effects	**A**
Prevention of future toxicity / side-effects	**B**
Maximum cumulative dose reached	**C**
Progressive disease (radiologically established)	**D**
Progressive disease (clinical progression)	**E**
Clinical deterioration necessitating stopping further treatment	**F**
Absent overall risk-benefit of continued treatment (patient´s or family´s decision)	**G**
Absent overall risk-benefit of continued treatment (physician´s decision)	**H**
Treatment completed as per planning (received all planned cycles of the treatment)	**I**
Other	**J**
Death **[HIDE IF E3=1]**	**K**

IF E115K, E115L E115M, E115N OR E115 O = nal-IRI or Onivid or MM-398 AND E130=A, D, E, K THEN Display Adverse Event Forms

[GO BACK TO DASHBOARD]

Appendix 1

[LINK ECOG]

ECOG SCALE

Karnofsky Status	Karnofsky Grade	ECOG Grade	ECOG
Normal, no complaints	100	0	Fully active, able to carry on all pre-disease performance without restriction
Able to carry on normal activities. Minor signs or symptoms of disease	90	1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
Normal activity with effort	80	1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
Care for self. Unable to carry on normal activity or to do active work	70	2	Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours
Requires occasional assistance, but able to care for most of his needs	60	2	Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours
Requires considerable assistance and frequent medical care	50	3	Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours
Disabled. Requires special care and assistance	40	3	Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours
Severly disabled. Hospitalisation indicated though death nonimminent	30	4	Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair
Very sick. Hospitalisation necessary. Active supportive treatment	20	4	Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair

necessary			
Moribund	10	4	Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair
Dead	0	5	Dead