

# ACTIN Report (research use only)

PATIENT  
EXAMPLE-CRC-01  
  
REPORT DATE  
17-Sep-2025

Gender: **Female** | Birth year: **1946** | WHO: **0**

Tumor: **Colorectum (cecum) carcinoma** | Lesions: **Lung, Peritoneal** | Stage: **IV**

## Clinical summary

Relevant systemic treatment history	<b>None</b>	
Relevant other oncological history	11/2021	<b>Hemicolecction right (Cecum)</b>
Previous primary tumor	<b>Skin squamous cell carcinoma (diagnosed 6/2016, last treatment 8/2016, considered non-active)</b>	
Relevant non-oncological history	1/2019	<b>Cerebrovascular accident</b>

## Recent molecular results

### NGS & MSI Panel (15-Jan-2023)

Tumor mutational burden	<b>TMB 8 mut/Mb</b>
Microsatellite (in)stability	<b>Stable</b>
Driver mutations	<b>KRAS G12D</b>

### Trial-relevant IHC results

PD-L1	<b>Score &lt; 50%</b>
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## Standard-of-care options considered potentially eligible

Treatment	Literature efficacy evidence	Real-world efficacy evidence	Warnings
<b>FOLFIRI</b>	<u><a href="#">PHASE-3-CRC</a></u>		
	<b>PFS:</b> 10.0 months (95% CI: 10.0-12.0)	<b>PFS:</b> 13.3 months, IQR: 12.6	
	<b>OS:</b> 25.0 months (95% CI: 25.0-30.0)	<b>OS:</b> 22.2 months, IQR: 24.8	

## Phase 2/3+ trials in Other that are open and potentially eligible (0)

Trial	Cohort	Molecular	Sites	Warnings
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## Phase 1 (or unknown phase) trials in Other that are open and potentially eligible (0)

Trial	Cohort	Molecular	Sites	Warnings
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## International trials that are open and potentially eligible (1 cohort from 1 trial)

Trial	Cohort	Molecular	Sites
<u><a href="#">KRAS-G12D-TRIAL</a></u>	<b>KRAS G12D</b>	<b>KRAS G12D</b>	<b>NL: Utrecht, Germany: Stuttgart</b>

International trials are matched solely on molecular event and tumor type (clinical data excluded).

## Molecular Details

### NGS & MSI Panel (15-Jan-2023)

Biopsy location	Lung
Tumor mutational burden	TMB 8 mut/Mb
Microsatellite (in)stability	Stable
Driver mutations	KRAS G12D

### IHC results

Ki67	Positive, score 90%
PD-L1	Score < 50%

### Molecular history

Event	Description	Date	Panel
KRAS G12D (Tier III)	Mutation (cancer-associated variant) Loss of function	VAF 0.2232%	
TMB		8.0	
MSI		Stable	

## Efficacy evidence

### Standard of care options considered potentially eligible

The following standard of care treatment(s) could be an option for this patient. For further details per study see 'SOC literature details' section in extended report.

Treatment	Literature efficacy evidence																
FOLFIRI	<p><a href="#">PHASE-3-CRC</a></p> <p><b>Patient characteristics:</b></p> <table border="1"> <tr> <td>WHO/ECOG</td><td>0: 100, 1: 80, 2: 20, 3: 0, 4: 0</td></tr> <tr> <td>Primary tumor location</td><td>Left: 145, Both or unknown: 10, Right: 45</td></tr> <tr> <td>Mutations</td><td>KRAS exon 2 wild-type 200/200</td></tr> <tr> <td>Metastatic sites</td><td>Liver only: 58 (32.0%), Lung only: 10 (6.0%)</td></tr> <tr> <td>Previous systemic therapy</td><td>35/200</td></tr> <tr> <td>Prior therapies</td><td>Adjuvant chemotherapy</td></tr> <tr> <td><b>Median PFS:</b></td><td>10.0 months (95% CI: 10.0-12.0)</td></tr> <tr> <td><b>Median OS:</b></td><td>25.0 months (95% CI: 25.0-30.0)</td></tr> </table>	WHO/ECOG	0: 100, 1: 80, 2: 20, 3: 0, 4: 0	Primary tumor location	Left: 145, Both or unknown: 10, Right: 45	Mutations	KRAS exon 2 wild-type 200/200	Metastatic sites	Liver only: 58 (32.0%), Lung only: 10 (6.0%)	Previous systemic therapy	35/200	Prior therapies	Adjuvant chemotherapy	<b>Median PFS:</b>	10.0 months (95% CI: 10.0-12.0)	<b>Median OS:</b>	25.0 months (95% CI: 25.0-30.0)
WHO/ECOG	0: 100, 1: 80, 2: 20, 3: 0, 4: 0																
Primary tumor location	Left: 145, Both or unknown: 10, Right: 45																
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Metastatic sites	Liver only: 58 (32.0%), Lung only: 10 (6.0%)																
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Prior therapies	Adjuvant chemotherapy																
<b>Median PFS:</b>	10.0 months (95% CI: 10.0-12.0)																
<b>Median OS:</b>	25.0 months (95% CI: 25.0-30.0)																

### PHASE-3-CRC

**Study:** PHASE-3-CRC, Phase III, Adjuvant

**Molecular requirements:** None

**Therapies:** FOLFIRI+Cetuximab, FOLFIRI

#### Patient characteristics:

	Cetuximab + FOLFIRI (n=100)	FOLFIRI (n=200)
Age (median [range])	65.0 [40-75]	65.0 [30-75]
Sex	Male: 50	Male: 120

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	Female: 50	Female: 80
Race	NA	NA
Region	Europe: 100 patients	Europe: 200 patients
WHO/ECOG	0: 80, 1: 10, 2: 10, 3: 0, 4: 0	0: 100, 1: 80, 2: 20, 3: 0, 4: 0
Primary tumor location	Left: 78 Both or unknown: 3 Right: 19	Left: 145 Both or unknown: 10 Right: 45
Mutations	KRAS exon 2 wild-type 100/100	KRAS exon 2 wild-type 200/200
Metastatic sites	Liver only: 62 (62.0%), Lung only: 4 (4.0%)	Liver only: 58 (32.0%), Lung only: 10 (6.0%)
Time of metastases	Unknown	Unknown
Previous systemic therapy	30/100	35/200
Prior therapies	Adjuvant chemotherapy	Adjuvant chemotherapy

## Primary endpoints:

Cetuximab + FOLFIRI	FOLFIRI	Hazard ratio (HR) / Odds Ratio (OR)	P value
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Median follow-up for PFS was 70 months

## Secondary endpoints:

Cetuximab + FOLFIRI	FOLFIRI	Hazard ratio (HR) / Odds Ratio (OR)	P value
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Median Overall Survival (95% CI)	35.0 (25.0 - 40.0)	25.0 months (25.0 - 30.0)	0.75 (0.6 - 0.95)	p = 0.011
Median Progression-Free Survival (95% CI)	10.0 (10.0 - 12.0)	10.0 months (10.0 - 12.0)	0.99 (0.8 - 1.25)	p = 1

Median follow-up for PFS was 70 months

## Treatment decisions (percentage of population assigned to systemic treatment) in NCR real-world data set

	All (n=9207)	Age 73-83y (n=2727)	WHO 1 (n=2828)	RAS positive (n=2760)	Liver only lesions (n=2715)
FOLFIRI	38.5%	23.8%	37.9%	44.6%	39.5%

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## Median overall survival (OS) in months in NCR real-world data set

	All (n=9207)	Age 73-83y (n=2727)	WHO 1 (n=2828)	RAS positive (n=2760)	Liver only lesions (n=2715)
FOLFIRI	<b>16.1</b> , IQR: 18.2 (n=3543)	<b>15.4</b> , IQR: 18.2 (n=649)	<b>14.8</b> , IQR: 16.3 (n=1071)	<b>15.8</b> , IQR: 14.2 (n=1230)	<b>16.5</b> , IQR: 17.4 (n=1073)

## Median progression-free survival (PFS) in months in NCR real-world data set

	All (n=5018)	Age 73-83y (n=1330)	WHO 1 (n=1623)	RAS positive (n=1822)	Liver only lesions (n=1534)
FOLFIRI	<b>8.2</b> , IQR: 5.5 (n=2106)	<b>8</b> , IQR: 6.1 (n=340)	<b>7.9</b> , IQR: 5 (n=661)	<b>8</b> , IQR: 4.7 (n=836)	<b>8.3</b> , IQR: 5.3 (n=652)

## Explanation:

These tables only show treatments that are considered standard of care (SOC) in colorectal cancer in the Netherlands.

The 'All' column shows results in NCR patients who were previously untreated, diagnosed with colorectal cancer with distant metastases and treated systemically without surgery, for whom the treatment could be categorized in SOC treatments.

The 'Age', 'WHO', 'RAS' and 'Lesions' columns show results based on patients from the 'All' population, filtered for equal WHO, similar age, equal RAS status or equal lesion localization, respectively.

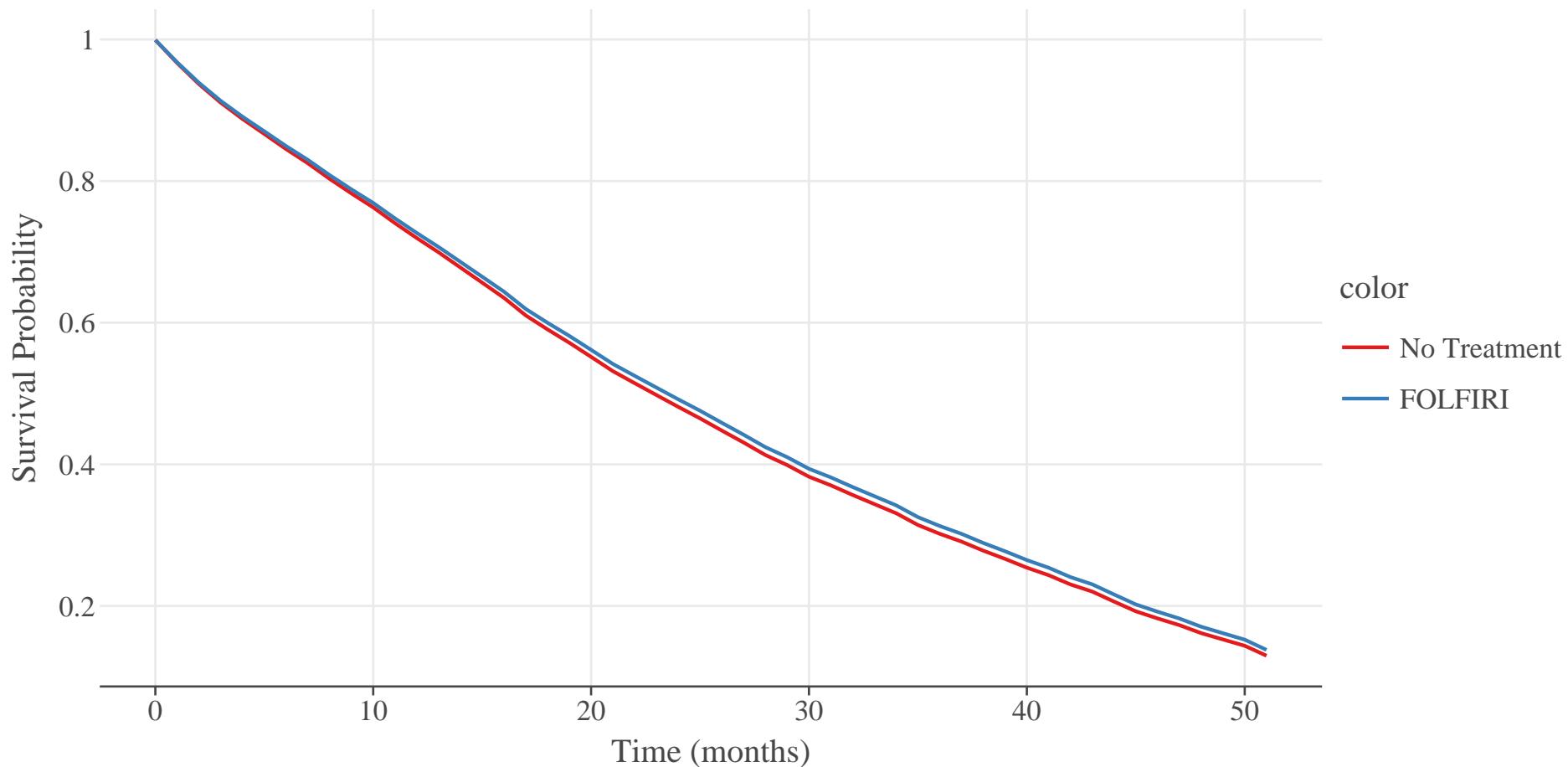
'PFS' is calculated as the duration from the date on which the first compound of the treatment was administered, until first progression.

'OS' is calculated as the duration from the date on which the first compound of the treatment was administered, until death from any cause.

When patient number is too low (n <= 20) to predict PFS or OS, "NA" is shown.

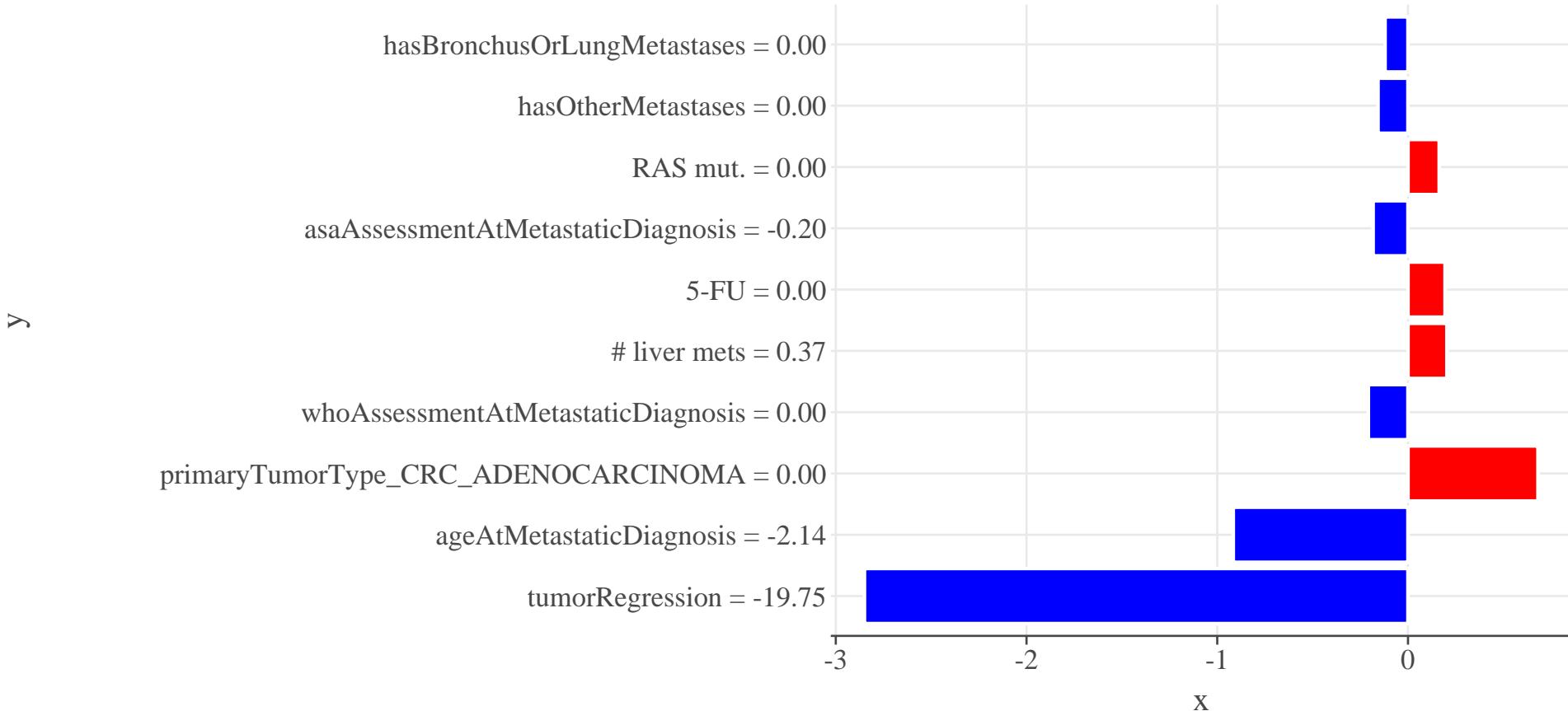
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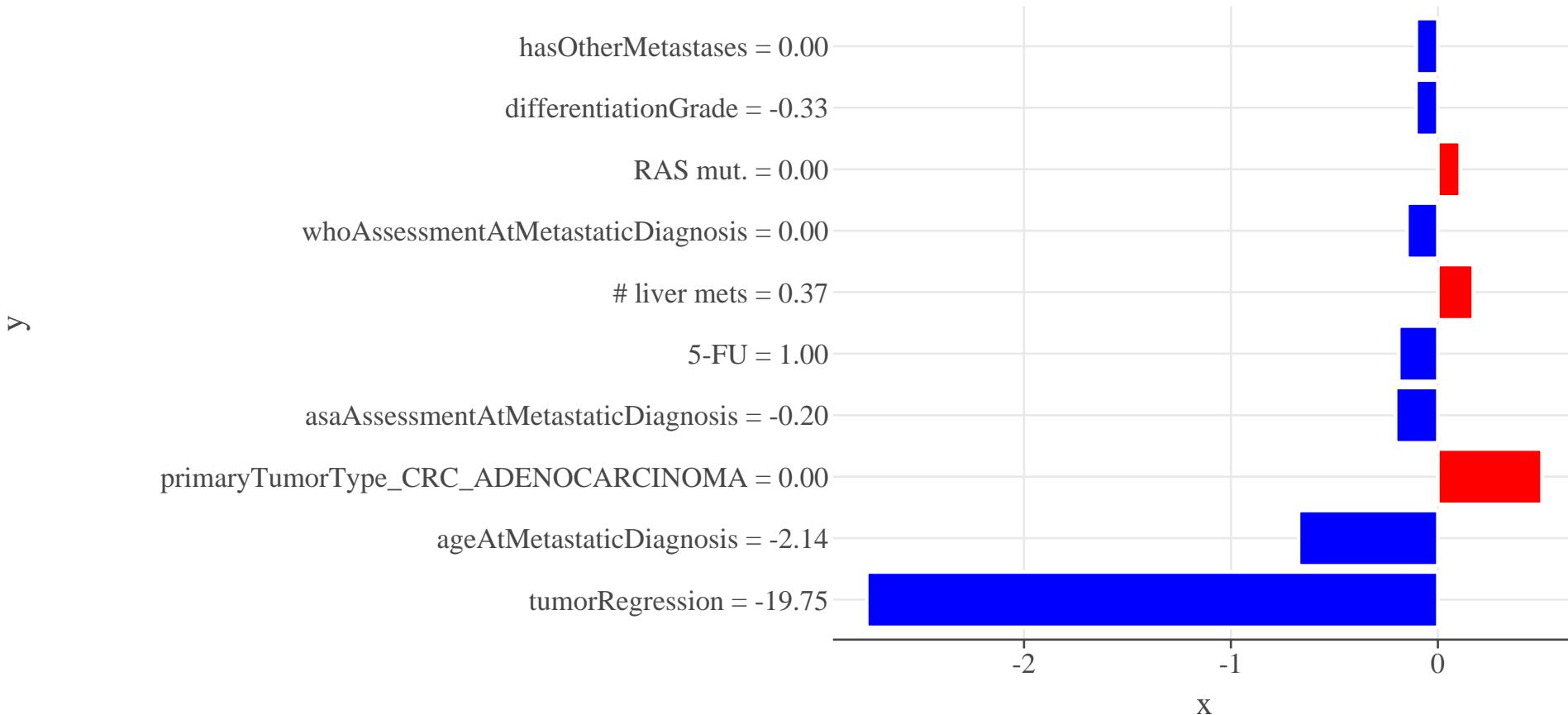


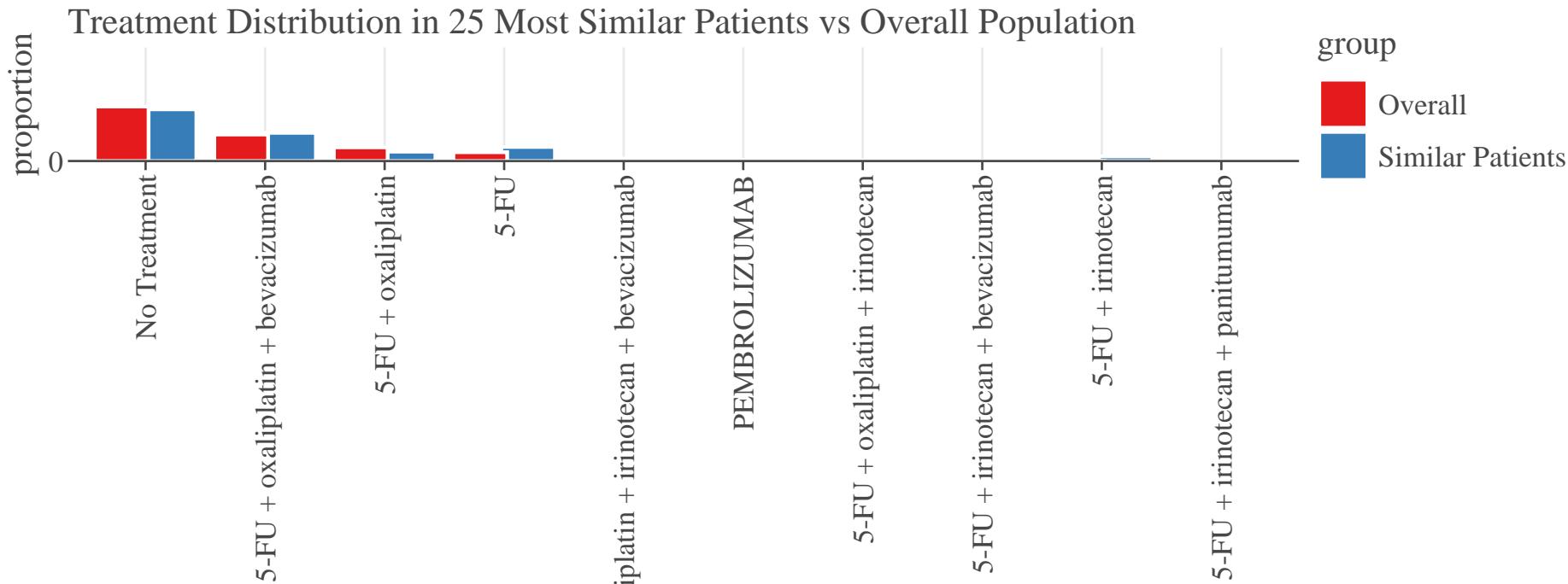
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## SHAP values for treatment: No Treatment



## SHAP values for treatment: FOLFIRI





#### Resistance evidence

Treatment	Mutation	Evidence source	Evidence level	Found in molecular analysis
FOLFIRI	GENE S11C	[1]	D	Yes

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## On label clinical evidence

Event	CKB Event	Level A	Level B	Level C	Level D
None					

## Off label clinical evidence

Event	CKB Event	Level A	Level B	Level C	Level D
None					

## Efficacy evidence description

None

## Treatment ranking

Treatment	Events	Score
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## Clinical Details

### Clinical summary

Relevant systemic treatment history	<b>None</b>	
Relevant other oncological history	<b>11/2021</b>	<b>Hemicolectomy right (Cecum)</b>
Previous primary tumor	<b>Skin squamous cell carcinoma (diagnosed 6/2016, last treatment 8/2016, considered non-active)</b>	
Relevant non-oncological history	<b>1/2019</b>	<b>Cerebrovascular accident</b>

### Patient current details (05-Mar-2023)

Unresolved toxicities grade => 2	<b>None</b>
Known allergies	<b>Morphine</b>
Recent surgeries	<b>12-Nov-2021 Hemicolectomy right</b>

### Tumor details (05-Mar-2023)

Measurable disease	<b>Yes</b>
Known lesions	<b>Lung, Peritoneal</b>
Unknown lesions	<b>Lymph node</b>
No lesions present	<b>CNS, Brain, Liver, Bone</b>

### Active medication details

Medication	Administration route	Start date	Stop date	Dosage	Frequency
None					

### Blood transfusions

Product	Date
ERTHROCYTES_FILTERED	10-Jan-2023

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## Trial Matching Details

### International trials that are open and potentially eligible (0)

Trial	Cohort	Molecular	Sites

### International trials that are open and potentially eligible (1 cohort from 1 trial)

Trial	Cohort	Molecular	Sites
<a href="#">KRAS-G12D-TRIAL</a>	KRAS G12D	KRAS G12D	NL: Utrecht, Germany: Stuttgart

International trials are matched solely on molecular event and tumor type (clinical data excluded).

### Trials and cohorts that are potentially eligible, but are closed (2)

Trial	Cohort	Molecular	Sites	Warnings
<a href="#">METC 01 IEMOEN</a>	Applies to all cohorts below  Dose escalation - monotherapy Dose expansion - monotherapy	None		Has not exhausted SOC

### Trials and cohorts that are considered ineligible (2)

Trial	Cohort	Molecular	Ineligibility reasons
<a href="#">METC 02 KAYRAS</a>	Applies to all cohorts below  Dose expansion - monotherapy - Colorectum Dose expansion - monotherapy - NSCLC	KRAS G12D	PD-L1 expression below minimum of 50.0  No lung non-small cell carcinoma

### Trials and cohorts that are not evaluable or ignored (0)

Trial	Cohort	Molecular	Sites	Configuration
None				

## Other trials & cohorts

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12/15 Gene and variant annotations and related content are powered by Genomenon Cancer Knowledgebase (CKB).

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## METC 02

Potentially eligible	No
Acronym	KAYRAS
Title	A phase 1/2 trial for first in-human usage of KAYRAS, a new specific KRAS G12D inhibitor in NSCLC and colorectal cancer
Reference	Evaluation
I-05	FAIL  PD-L1 expression below minimum of 50.0

## METC 02 - Dose expansion - monotherapy - NSCLC

Cohort ID	A
Potentially eligible?	No
Open for inclusion?	Yes
Has slots available?	Yes
Reference	Evaluation
I-02	FAIL  No lung non-small cell carcinoma

## METC 02 - Dose expansion - monotherapy - Colorectum

Cohort ID	B
Potentially eligible?	No
Open for inclusion?	Yes
Has slots available?	Yes

## METC 01

Potentially eligible	Yes
Acronym	IEMOEN
Title	Phase I first-in-human study to evaluate safety of IEMOEN, a new PD-L1 inhibitor in advanced solid tumors

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Reference	Evaluation
I-03	<span style="color: orange;">WARN</span> Has not exhausted SOC
E-01	<span style="color: green;">PASS</span> Has no other condition belonging to category autoimmune disease
E-02	<span style="color: green;">PASS</span> Hemoglobin above 6 mmol/L
E-03	<span style="color: green;">PASS</span> Neutrophils above 1.5
I-01	<span style="color: green;">PASS</span> Patient is at least 18 years old
I-02	<span style="color: green;">PASS</span> Has solid primary tumor Stage IV is considered metastatic

## METC 01 - Dose escalation - monotherapy

Cohort ID	<b>A</b>
Potentially eligible?	<b>Yes</b>
Open for inclusion?	<b>No</b>
Has slots available?	<b>No</b>

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## METC 01 - Dose expansion - monotherapy

Cohort ID	B
Potentially eligible?	Yes
Open for inclusion?	No
Has slots available?	No