

# 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>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	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	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>OS:</b> 25.0 months (95% CI: 25.0-30.0)	

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

None

## Phase 1/2 (or unknown phase) trials in NL that are open and potentially eligible (1 trial)

Trial	Cohort	Molecular	Sites	Warnings
<u><a href="#">KRAS-G12D-TRIAL</a></u>	<i>KRAS G12D</i>	<i>KRAS G12D</i>	<i>UMC Utrecht</i>	

Trials matched solely on molecular event and tumor type (no clinical data used) are shown in italicized, smaller font.

## 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
		2023-01-15
		NGS & MSI 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																
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Previous systemic therapy	35/200																
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<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:

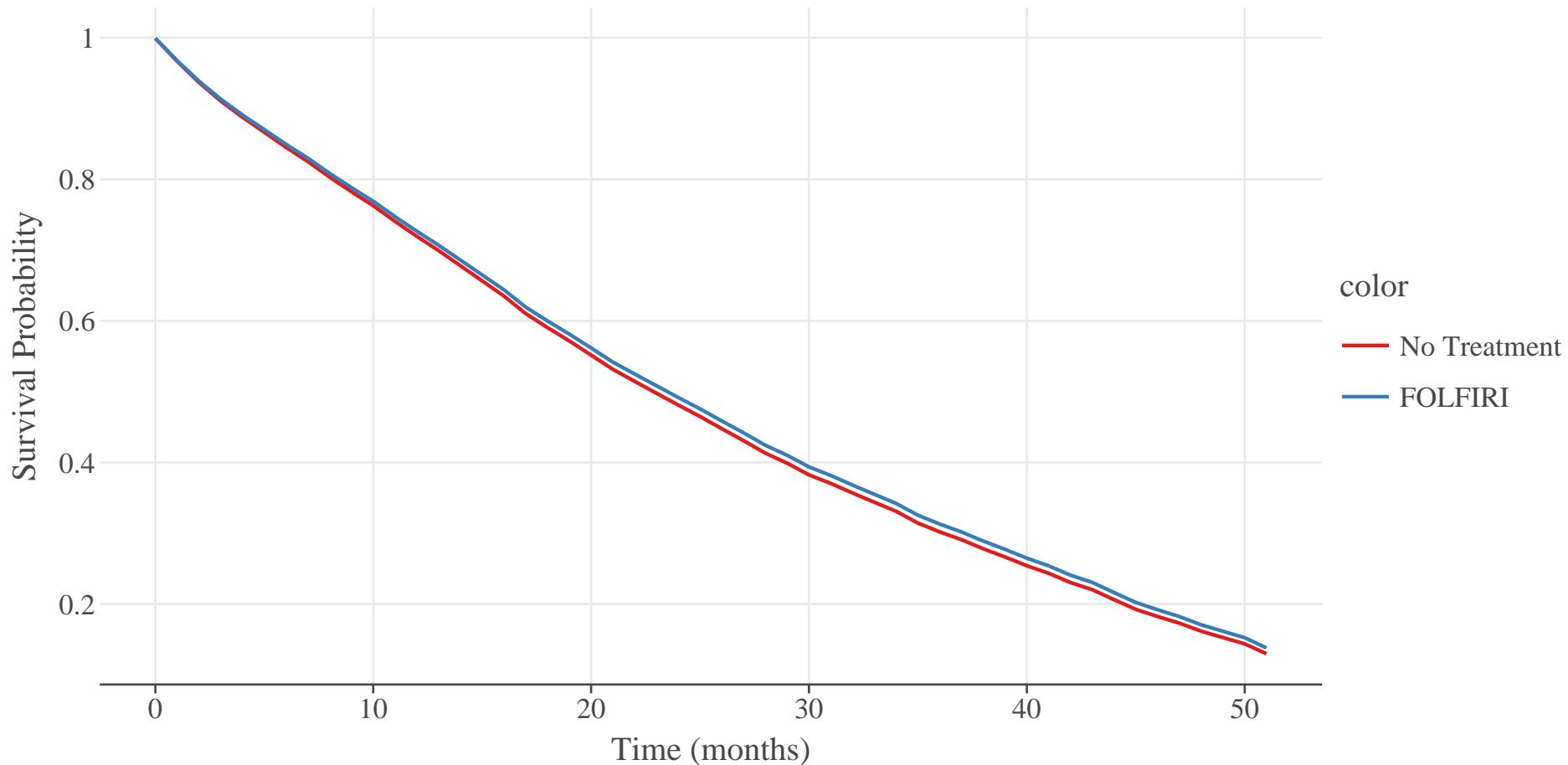
Cetuximab + FOLFIRI	FOLFIRI	Hazard ratio (HR) / Odds Ratio (OR)	P value
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Median Overall Survival (95% CI)	35.0 (25.0 - 40.0)	25.0 months (25.0 - 30.0)	0.75 (0.6 - 0.95)	p = 0.011
Median Progression-Free Survival (95% CI)	10.0 (10.0 - 12.0)	10.0 months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

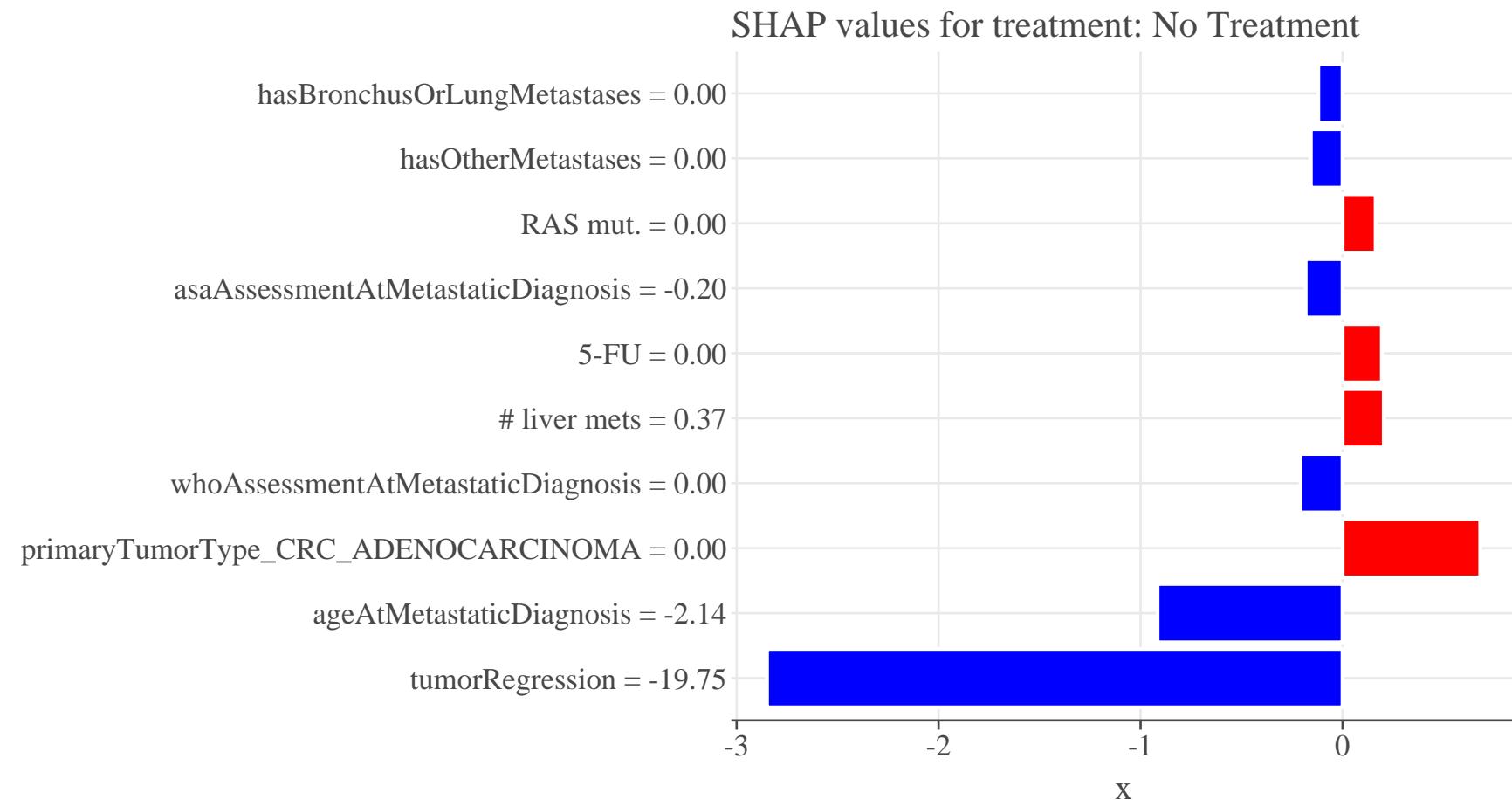
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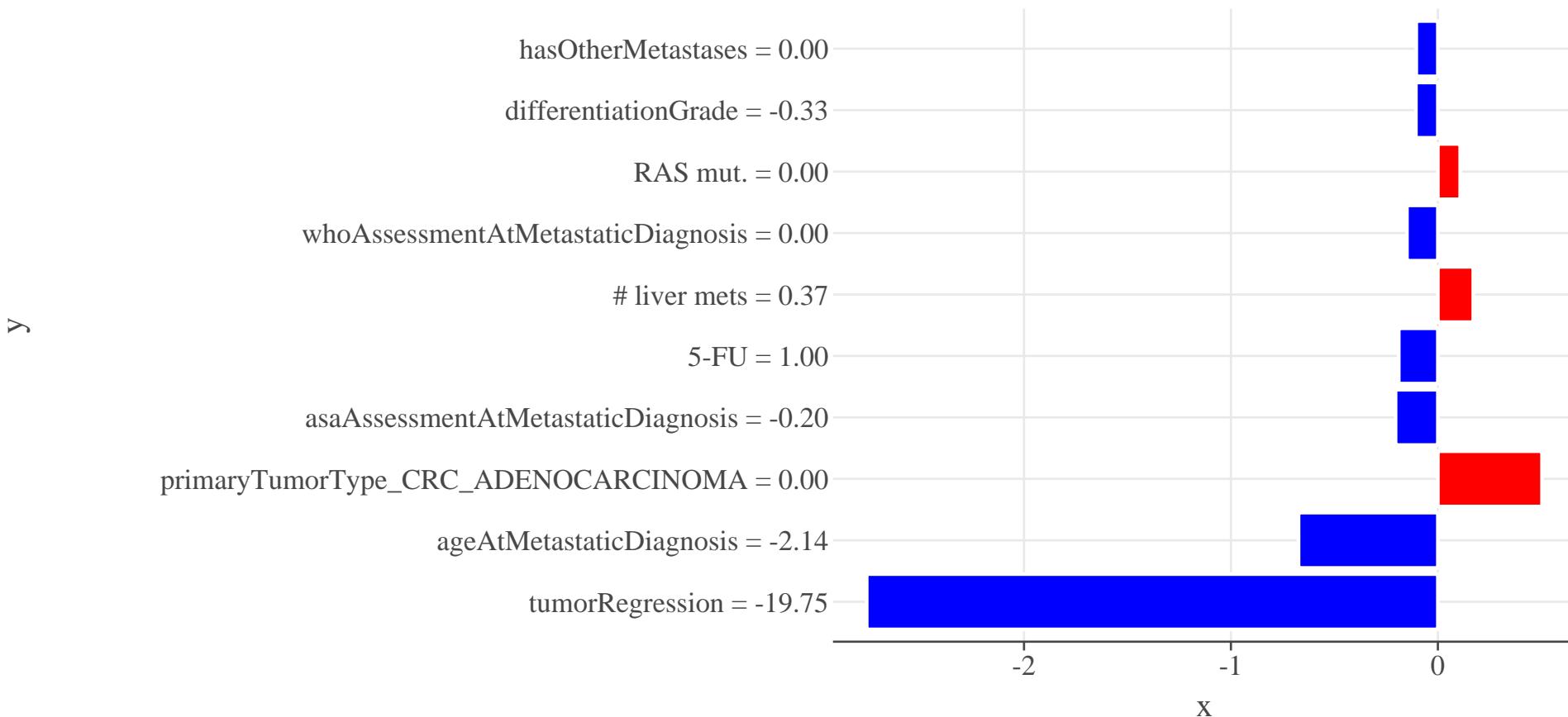
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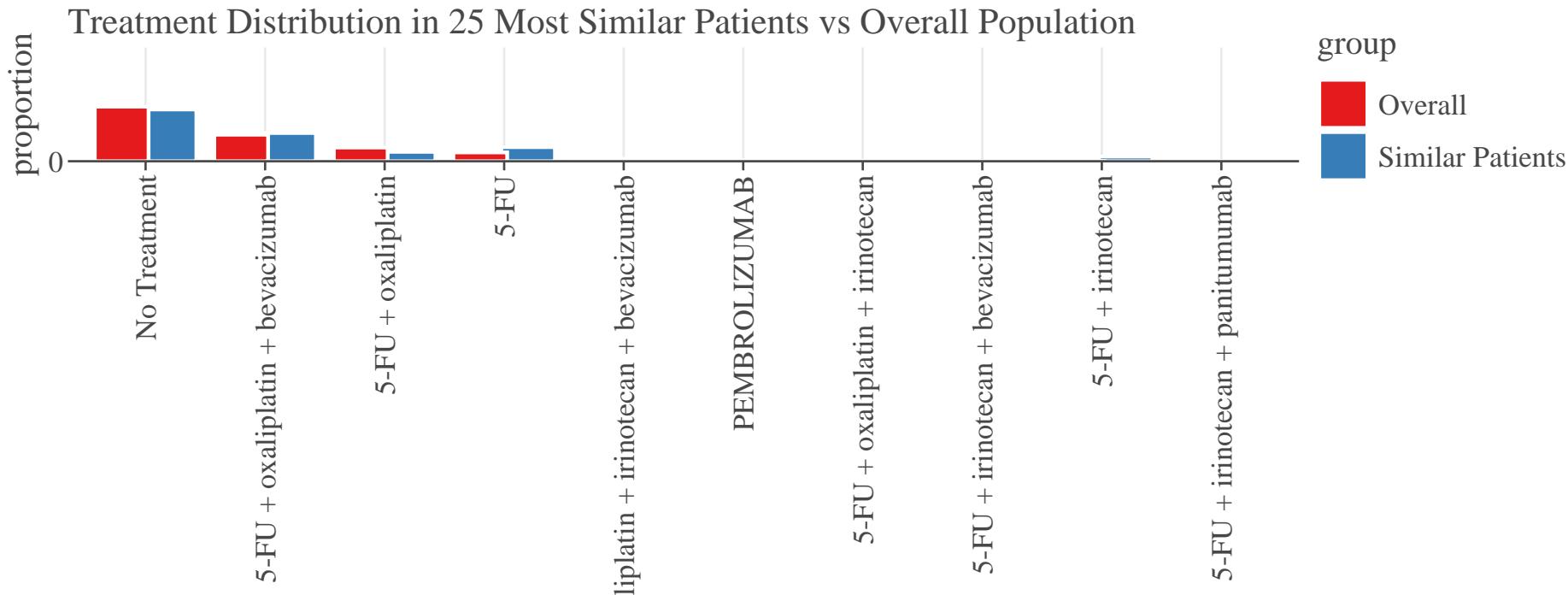


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## SHAP values for treatment: FOLFIRI





#### Resistance evidence

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

#### Treatment ranking

Event	Treatment	Score
8/13		

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## On label clinical evidence

None

## Off label clinical evidence

None

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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

None

### Blood transfusions

Product	Date
ERTHROCYTES_FILTERED	10-Jan-2023

## Trial Matching Details

### National trials that are open and potentially eligible (1 trial)

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

Trials in this table are matched solely on molecular event and tumor type (clinical data excluded).

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

None

### Trials and cohorts that are potentially eligible, but are closed (2 cohorts from 1 trial)

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 cohorts from 1 trial)

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 trials)

None

## Other trials & cohorts

### 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**

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Reference	Evaluation
I-05	FAIL  PD-L1 expression below minimum of 50.0

## METC 02 - Dose expansion - monotherapy - NSCLC

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

Reference	Evaluation
I-02	FAIL  No lung non-small cell carcinoma

## METC 02 - Dose expansion - monotherapy - Colorectum

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

## METC 01

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

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Reference	Evaluation
I-03	<b>WARN</b> Has not exhausted SOC
E-01	<b>PASS</b> Has no other condition belonging to category autoimmune disease
E-02	<b>PASS</b> Hemoglobin above 6 mmol/L
E-03	<b>PASS</b> Neutrophils above 1.5
I-01	<b>PASS</b> Patient is at least 18 years old
I-02	<b>PASS</b> 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>

## METC 01 - Dose expansion - monotherapy

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

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