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

Recent molecular results

NGS & MSI Panel (15-Jan-2023)

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

Trial-relevant IHC results

PD-L1	**Score < 50%**

Standard-of-care options considered potentially eligible

Treatment	Literature efficacy evidence	Real-world efficacy evidence	Warnings
FOLFIRI	PHASE-3-CRC		
	PFS: 10.0 months (95% CI: 10.0-12.0)	**PFS:** 13.3 months, IQR: 12.6	
	OS: 25.0 months (95% CI: 25.0-30.0)	**OS:** 22.2 months, IQR: 24.8	

Trials in Other that are open and potentially eligible (0)

Trial	Cohort	Molecular	Sites	Warnings

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

Trial	Cohort	Molecular	Sites
KRAS-G12D-TRIAL	*KRAS G12D*	*KRAS G12D*	*NL: Utrecht, Germany: Stuttgart*

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

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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	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

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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	PHASE-3-CRC **Patient characteristics:**

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

Median PFS: 10.0 months (95% CI: 10.0-12.0)

Median OS: 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

Median follow-up for PFS was 70 months

Secondary endpoints:

	Cetuximab + FOLFIRI	FOLFIRI	Hazard ratio (HR) / Odds Ratio (OR)	P value
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	**16.1**, IQR: 18.2 (n=3543)	**15.4**, IQR: 18.2 (n=649)	**14.8**, IQR: 16.3 (n=1071)	**15.8**, IQR: 14.2 (n=1230)	**16.5**, 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	**8.2**, IQR: 5.5 (n=2106)	**8**, IQR: 6.1 (n=340)	**7.9**, IQR: 5 (n=661)	**8**, IQR: 4.7 (n=836)	**8.3**, 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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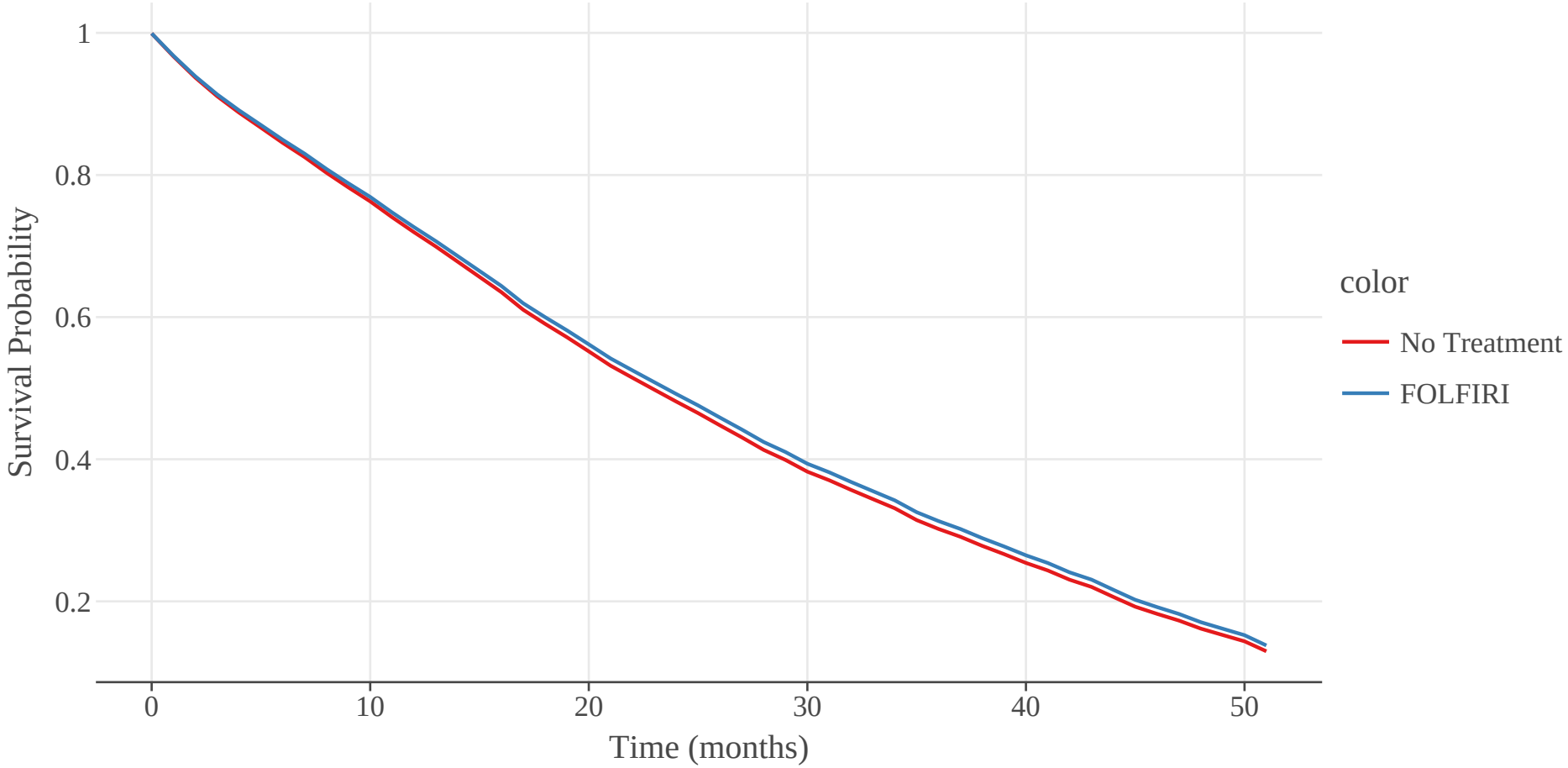

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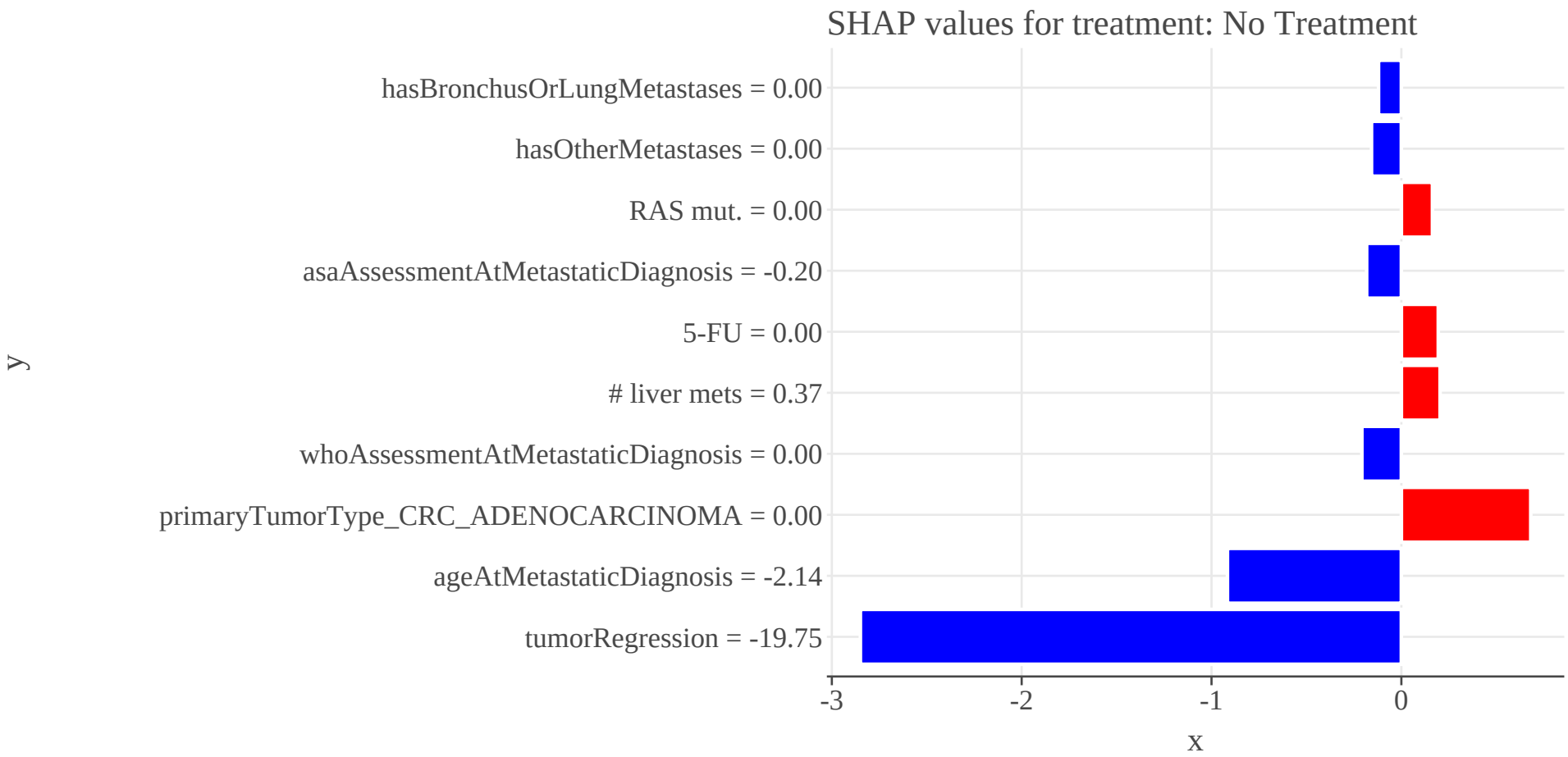

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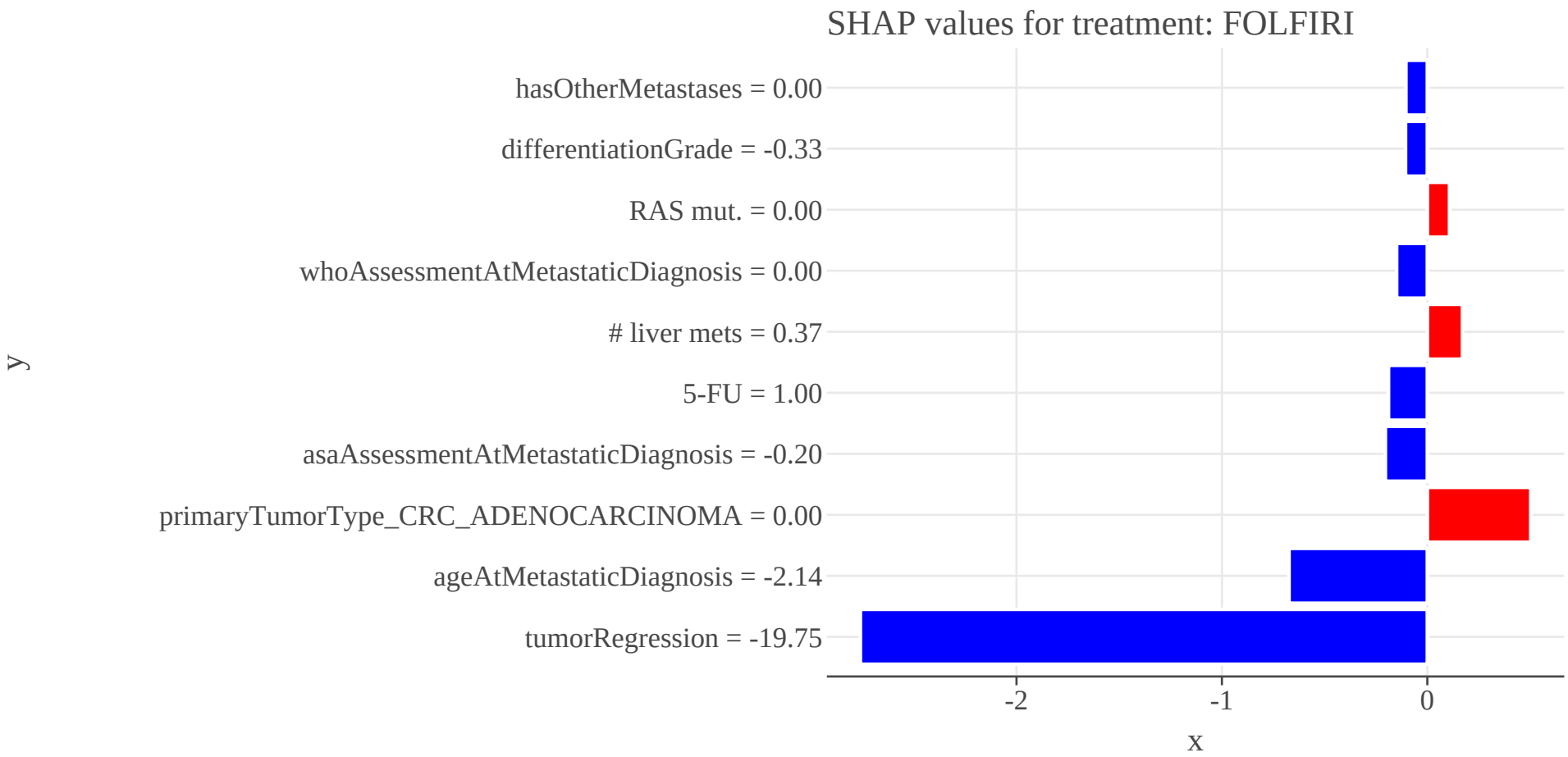

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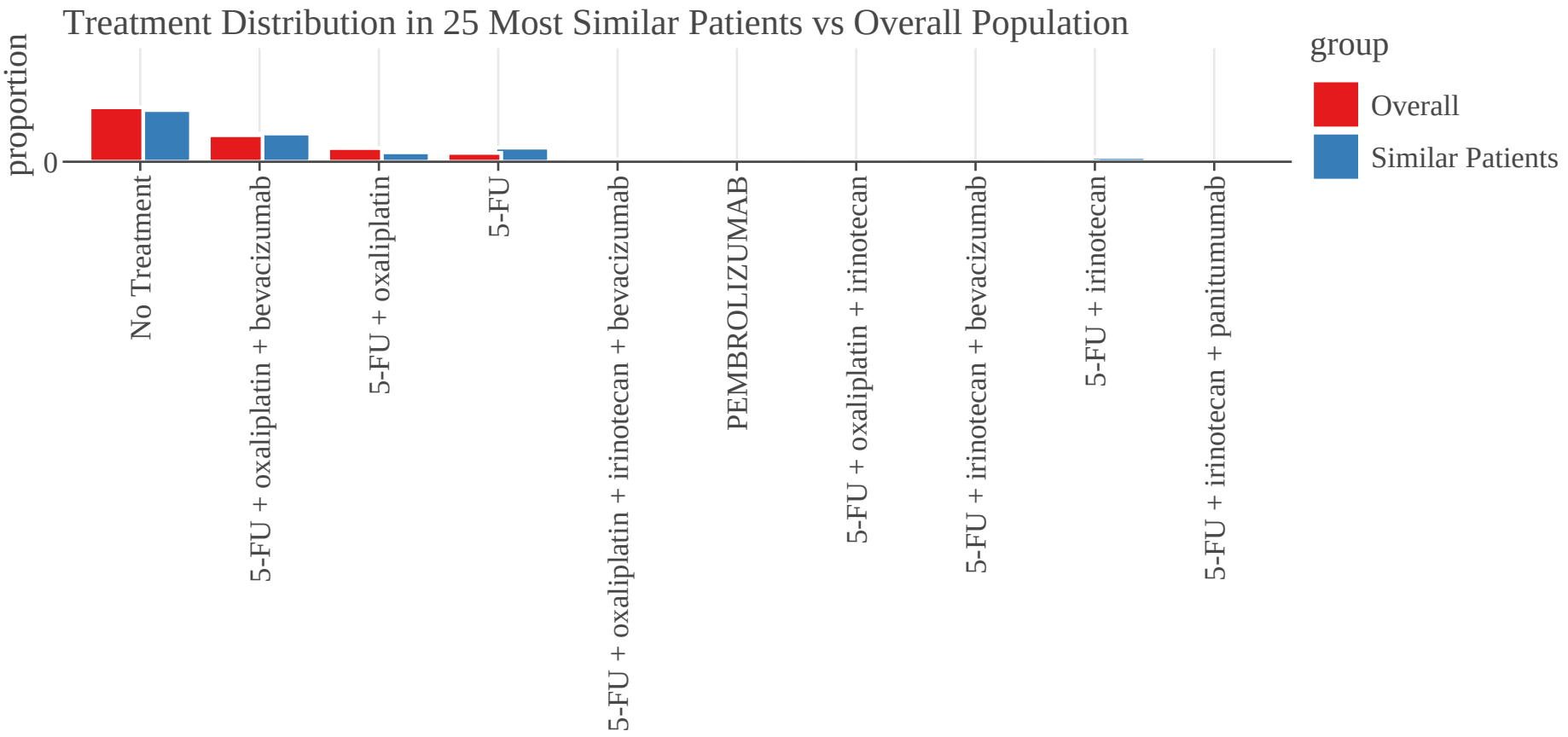

Resistance evidence

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

Patient current details (05-Mar-2023)

Unresolved toxicities grade => 2	**None**
Cancer-related complications	**Unknown**
Known allergies	**Morphine**
Recent surgeries	**12-Nov-2021 Hemicolectomy right**

Tumor details (05-Mar-2023)

Measurable disease	**Yes**
Known lesions	**Lung, Peritoneal**
Unknown lesions	**Lymph node**
No lesions present	**CNS, Brain, Liver, Bone**

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

Trials in Other that are open and potentially eligible (0)

Trial	Cohort	Molecular	Sites	Warnings

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

Trial	Cohort	Molecular	Sites
KRAS-G12D-TRIAL	*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
METC 01 IEMOEN	*Applies to all cohorts below*	None		Has not exhausted SOC
	Dose escalation - monotherapy			
	Dose expansion - monotherapy			

Trials and cohorts that are considered ineligible (2)

Trial	Cohort	Molecular	Ineligibility reasons
METC 02 KAYRAS	*Applies to all cohorts below*	KRAS G12D	PD-L1 expression below minimum of 50.0
	Dose expansion - monotherapy - Colorectum		
	Dose expansion - monotherapy - NSCLC		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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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	WARN Has not exhausted SOC
E-01	PASS Has no other condition belonging to category autoimmune disease
E-02	PASS Hemoglobin above 6 mmol/L
E-03	PASS Neutrophils above 1.5
I-01	PASS Patient is at least 18 years old
I-02	PASS Has solid primary tumor Stage IV is considered metastatic

METC 01 - Dose escalation - monotherapy

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

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METC 01 - Dose expansion - monotherapy

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

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