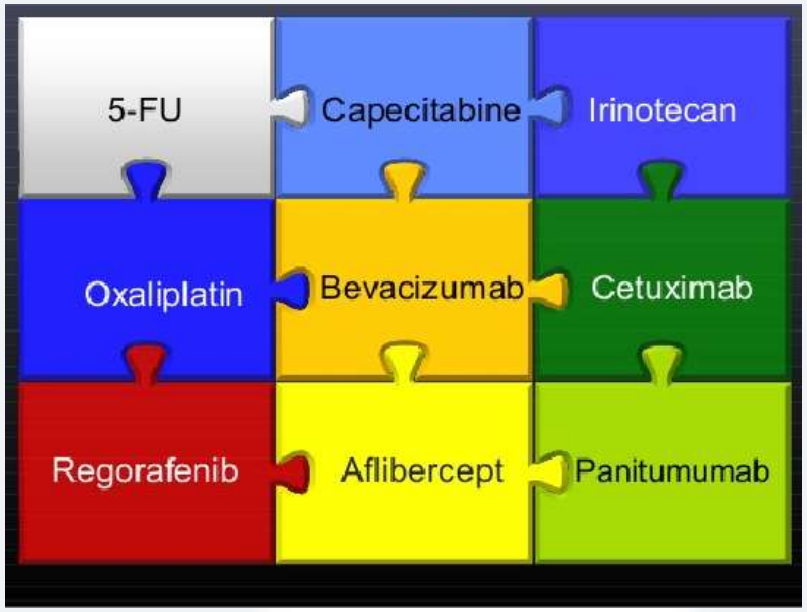
Mitä uutta kolorektaalisyövästä ?



Valtakunnalliset onkologiapäivät 2013

Tapio Salminen , TAYS

special article

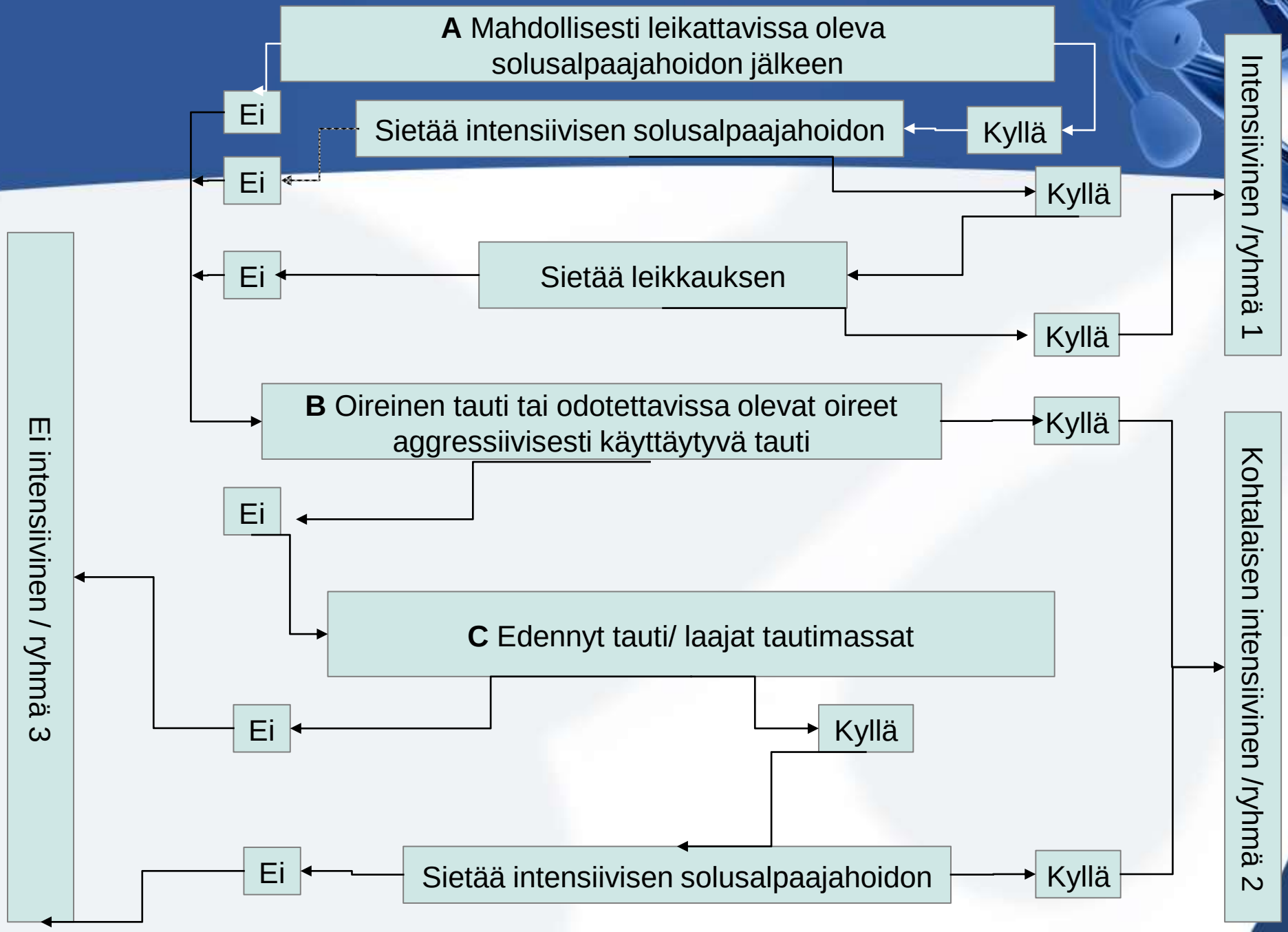
Annals of Oncology 23: 2479–2516, 2012
doi:10.1093/annonc/mds236

ESMO Consensus Guidelines for management of patients with colon and rectal cancer. A personalized approach to clinical decision making

H. J. Schmoll[1*], E. Van Cutsem[2], A. Stein[3], V. Valentini[4], B. Glimelius[5,6], K. Haustermans[7], B. Nordlinger[8,9], C. J. van de Velde[10], J. Balmana[11], J. Regula[12], I. D. Nagtegaal[13], R. G. Beets-Tan[14], D. Arnold[3], F. Ciardiello[15], P. Hoff[16,17], D. Kerr[18], C.H. Köhne[19], R. Labianca[20], T. Price[21], W. Scheithauer[22], A. Sobrero[23], J. Tabernero[24], D. Aderka[25], S. Barroso[26], G. Bodoky[27], J. Y. Douillard[28], H. El Ghazaly[29], J. Gallardo[30], A. Garin[31], R. Glynne-Jones[32], K. Jordan[1], A. Meshcheryakov[31], D. Papamichail[33], P. Pfeiffer[34], I. Souglakos[35], S. Turhal[36] & A. Cervantes[37]

Metastasoineen taudin hoidon valinnan periaatteet kolorektaalisyövässä

Ryhmä 0	R0 resekoitavissa oleva maksa tai keuhkometastaasi	Tavoitteena kuraatio, relapsin esto	Ei tarv. solusalpaajahoitoa tai kohtalaisen tehokas hoito
Ryhmä 1	Resektoimahdollisuus hoidon jälkeen Rajoittunut/paikallinen leviäminen Sietää ja kestää raskaan solusalpaajahoidon ja operatiivisen hoidon	Taudin mahdollisimman tehokas pienentäminen, intensiivinen hoito	Alussa mahdollisimman tehokas hoito
Ryhmä2	Laajalle levinnyt tauti, ei mahdollisuutta kuraatioon Taudin nopea eteneminen Tautiin liittyviä oireita tai odotettavissa oleva nopea kunnon huononeminen Kunnon puolesta mahdollisuus intensiiviseen hoitoon	Pyritään nopeaan tautimassan pienentämiseen Taudin etenemisen nopea kontrollointi	Aloitetaan tehokkaalla hoidolla, vähintään kahden solusalpaajan yhdistelmällä
Ryhmä 3	Taudin laaja levinneisyys, ei mahdollisuutta koskaan kuraatioon Ei merkittäviä tautiin liittyviä oireita tai odotettavissa olevaa kunnon nopeaa huononemista Yleiskunto estää intensiiviset hoidot	Taudin etenemisen rauhoittaminen Tautimuutosten pienentäminen vähemmän tärkeää Hoidon sivuvaikutusten vähäisyys tärkeää	Hoidon valinta ottaen huomioon tehokkuus ja sivuvaikutukset Seuranta harvoin Vuorottainen hoito, yksittäissolusalpaajahoito tai hyvin siedetty yhdistelmähoito. Harvoin kolmoishoitoa


A Mahdollisesti leikattavissa oleva solusalpaajahoidon jälkeen
Ei
Sietää intensiivisen solusalpaajahoidon
Kyllä
Ei
Kyllä
Ei
Sietää leikkauksen
Kyllä
Intensiivinen /ryhmä 1
B Oireinen tauti tai odotettavissa olevat oireet aggressiivisesti käyttäytyvä tauti
Kyllä
Ei
Kohtalaisen intensiivinen /ryhmä 2
C Edennyt tauti/ laajat tautimassat
Ei
Kyllä
Ei
Sietää intensiivisen solusalpaajahoidon
Kyllä
Ei intensiivinen / ryhmä 3

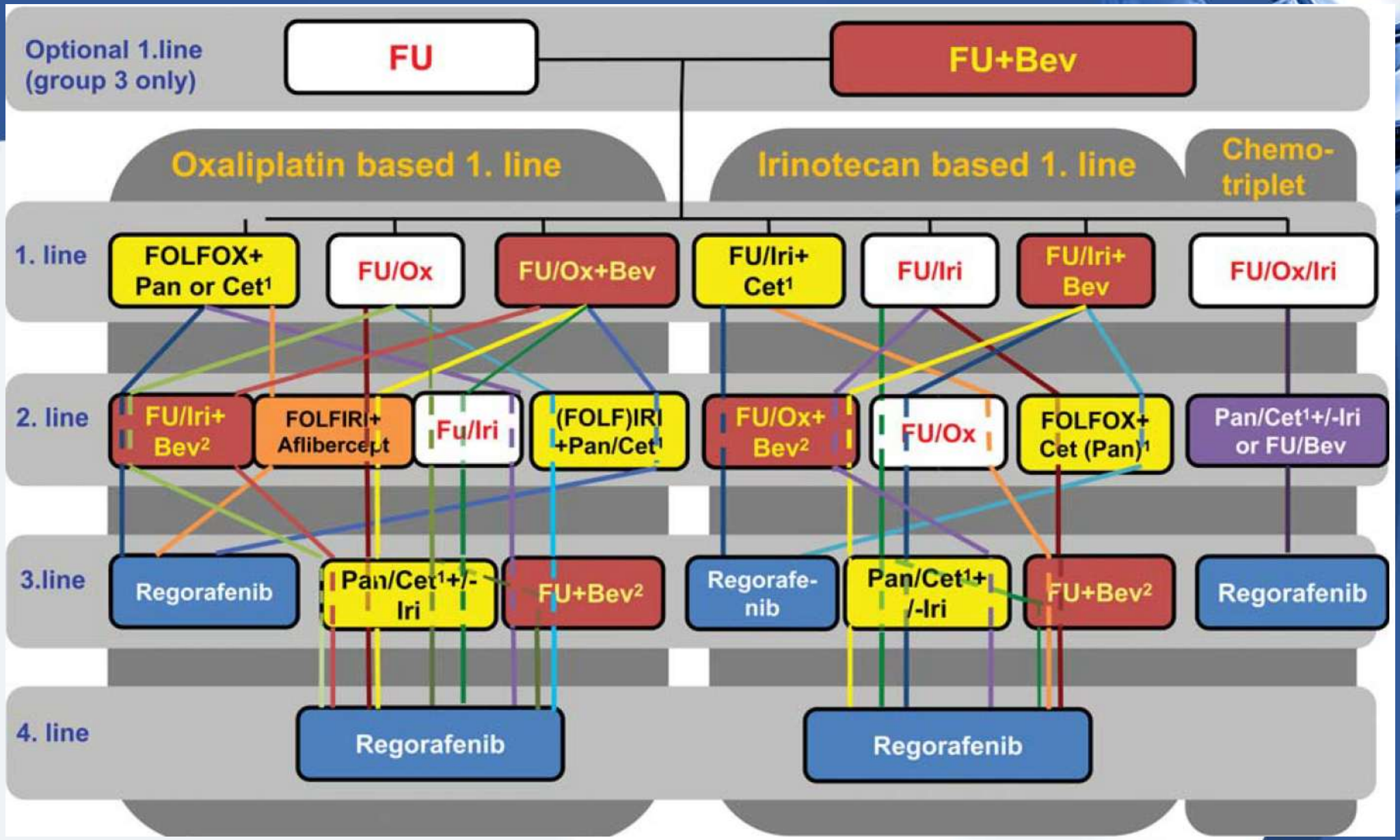


Figure 8. Proposal for sequence of salvage-chemotherapy. (1) only KRAS wt; (2) continuation of Bev not beyond second line, in case of optional first line and first line both with Bev; FU, fluoropyridmidines; Iri, irinotecan; Ox, oxaliplatin; Bev, bevacizumab; Afli, aflibercept; Cet, cetuximab; Pan, panitumumab.

• NCCN erilliset paksu- ja peräsuoli suositukset

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)

Colon Cancer

Version 3.2013

NCCN.org

Continue

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)

Rectal Cancer

Version 4.2013

NCCN.org

IMPORTANT NOTE REGARDING LEUCOVORIN SHORTAGE, PLEASE SEE MS-17

Continue

NCCN National Comprehensive Cancer Network®

NCCN Guidelines Version 3.201
Colon Cancer

PRINCIPLES OF RISK ASSESSMENT FOR

- Patient/physician discussion regarding the potential risks of therapy compared to potential benefits, including prognosis. This should include discussion of evidence supporting treatment, assumptions of benefit from indirect evidence, morbidity associated with treatment, high-risk characteristics, and patient preferences.
- When determining if adjuvant therapy should be administered, the following should be taken into consideration:
  - Number of lymph nodes analyzed after surgery (<12)
  - Poor prognostic features (eg, poorly differentiated histology [exclusive of those that are MSI-H]; lymphatic/vascular invasion; bowel obstruction; perineural invasion; localized perforation; close, indeterminate, or positive margins)
  - Assessment of other comorbidities and anticipated life expectancy.
- The benefit of adjuvant chemotherapy does not improve survival by more than 5%.
- The panel recommends that MMR protein testing be performed for all patients younger than 50 years with colon cancer, based on an increased likelihood of Lynch syndrome in this population. MMR testing should also be considered for all patients with stage II disease, because stage II MSI-H patients may have a good prognosis and do not benefit from 5-FU adjuvant therapy.[4]

- The panel recommends that MMR protein testing be performed for all patients younger than 50 years with colon cancer, based on an increased likelihood of Lynch syndrome in this population. MMR testing should also be considered for all patients with stage II disease, because stage II MSI-H patients may have a good prognosis and do not benefit from 5-FU adjuvant therapy.[4]

[1] Benson III AB, Schrag D, Somerfield MR, et al. American Society of Clinical Oncology recommendations on adjuvant chemotherapy for stage II colon cancer. J Clin Oncol 2004;16:3408-3419.

[2] Figueredo A, Charette ML, Maroun J, et al. Adjuvant therapy for stage II colon cancer: a systematic review from the cancer care ontario program in evidence-based care's gastrointestinal cancer disease site group. J Clin Oncol 2004;16:3395-3407.

[3] Gill S, Loprinzi CL, Sargent DJ, et al. Pooled analysis of fluorouracil-based adjuvant therapy for stage II and III colon cancer: who benefits and by how much? J Clin Oncol 2004;22:1797-1806.

Liitännäishoidon arviota helpottamaan?

- http://www.adjuvantonline.com/
- http://www.mayoclinic.com/calcs/
- http://www.mskcc.org/cancer-care/adult/colorectal/prediction-tools
- http://nomograms.mskcc.org/Colorectal/
- http://www.lifemath.net/cancer/coloncancer/outcome/index.php
- http://www3.mdanderson.org/app/medcalc/index.cfm?pagename=coloncancer

Phase III Neurotoxicity Study: CaMg vs CaMg/Placebo vs Placebo in Colon Cancer

Patients with resected colon cancer, no residual disease, no pre-existing PN (N = 362); oxaliplatin 85 mg/m^2 q2w

→

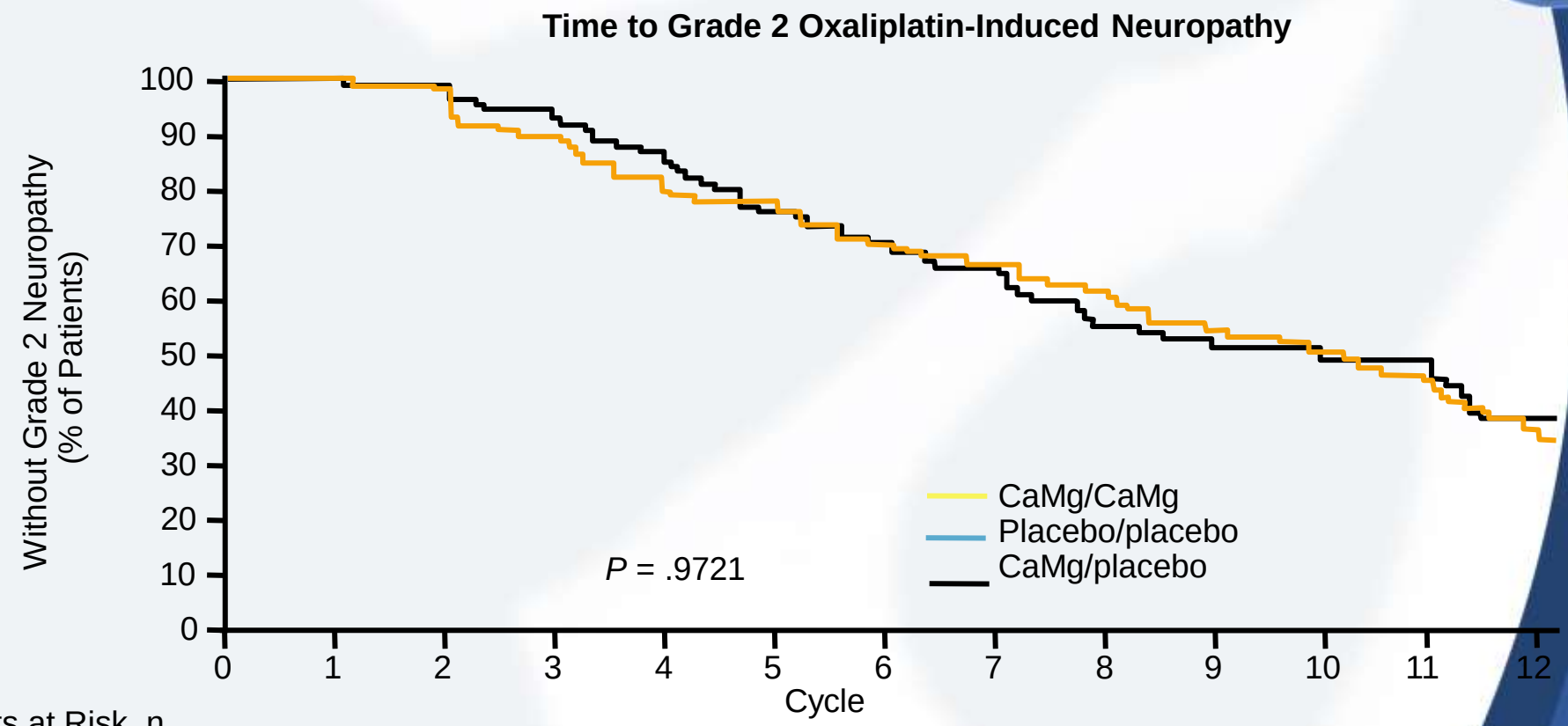
- CaMg before and after chemo (baseline n = 118; primary endpoint n = 110)
- Placebo before and after chemo (baseline n = 119; primary endpoint n = 106)
- CaMg before chemo, placebo after chemo (baseline n = 116; primary endpoint n = 110)

- Primary endpoint: CIPN20 AUC during 12 cycles chemotherapy

Oxaliplatin Regimen, %	Placebo/Placebo	CaMg/Placebo	CaMg/CaMg
FOLFOX4	8	7	6
mFOLFOX6	92	93	94

Loprinzi CL, et al. ASCO 2013. Abstract 3501. Used without permission.

Neurotoxicity Study of CaMg vs CaMg/ Placebo vs Placebo in Colon Cancer: Results



Pts at Risk, n													
CaMg/CaMg	110	110	107	99	90	76	67	58	47	43	39	35	19
Placebo/Placebo	107	106	103	93	84	78	70	63	56	48	41	37	18
CaMg/Placebo	111	108	101	94	89	77	65	61	55	46	40	36	13

IV CaMg did not prevent oxaliplatin-induced neuropathy

Loprinzi CL, et al. ASCO 2013. Abstract 3501. Used with permission.

Oksaliplatinan neurotoksisuus eri fluoropyrimidiinin kanssa

Annals of Oncology 23: 3116–3122, 2012
doi:10.1093/annonc/mds208

Peripheral neurotoxicity of oxaliplatin in combination with 5-fluorouracil (FOLFOX) or capecitabine (XELOX): a prospective evaluation of 150 colorectal cancer patients

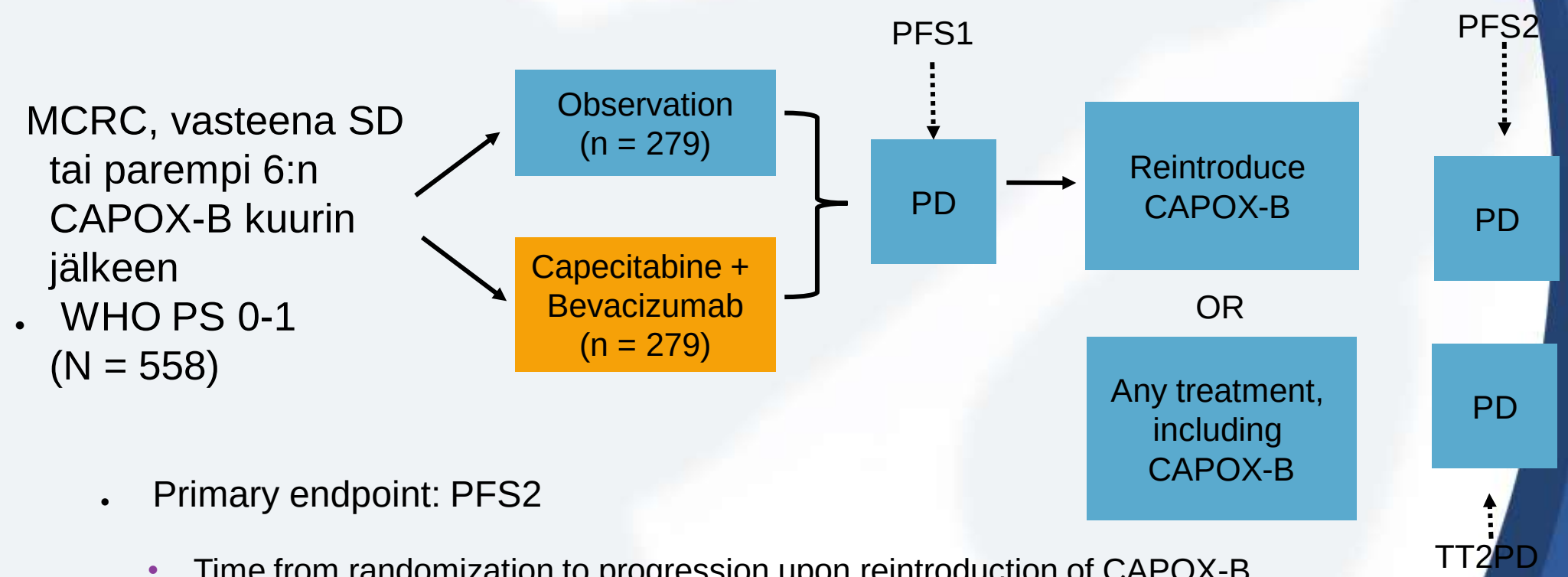
A. A. Argyriou[1,2], R. Velasco[9], C. Briani[3], G. Cavaletti[4], J. Bruna[9], P. Alberti[4], M. Cacciavillani[5], S. Lonardi[6], C. Santos[7], D. Cortinovis[8], M. Cazzaniga[8] & H. P. Kalofonos[9*]

[1]Department of Neurology, 'Saint Andrew's" State General Hospital of Patras, Patras; [2]Department of Medicine-Division of Clinical Oncology, University Hospital of Patras, Rion-Patras, Greece; [3]Department of Neurosciences, University of Padova, Padova; [4]Department of Neuroscience and Biomedical Technology, University of Milan-Bicocca, Monza; ; [5]Data Medica Group, EMG Unit, CEMES, Padova; [6]Oncology Unit 1, Veneto Oncology Institute - IRCCS, Padova, Italy; [7]Department of Oncology-Unit of Colorectal Cancer, University Hospital of Bellvitge-ICO Duran i Reynals, Barcelona, Spain; [8]Department of Oncology, S. Gerardo Hospital, Monza, Italy; [9]Department of Neurology-Unit of Neuro-Oncology, University Hospital of Bellvitge-ICO Duran i Reynals, Barcelona, Spain

Received 28 March 2012; revised 15 May 2012; accepted 22 May 2012

Conclusion: The incidence of acute neurotoxicity during FOLFOX-4 therapy is similar to XELOX. However, it seems that FOLFOX-4 is more neurotoxic than XELOX in terms of cumulative OXA-IPN, despite comparable OXA cumulative dose.

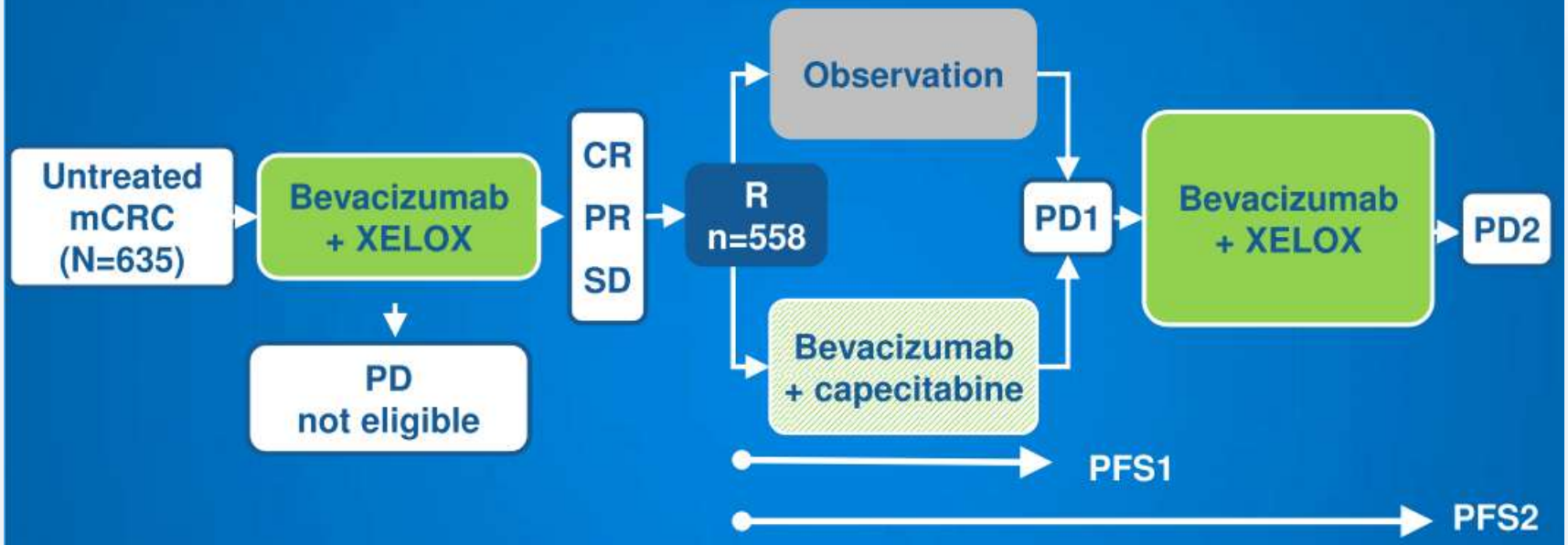
Faasi III CAIRO-3 : Ylläpito kapesitabiini + bevasitsumabi vs seuranta metastasoineessa kolorektaalisyövässä



- Primary endpoint: PFS2
  - Time from randomization to progression upon reintroduction of CAPOX-B
  - PFS2 considered equal to PFS1 in patients who do not receive CAPOX-B again (for any reason)
- Median follow-up: 40 mos

Koopman M, et al. ASCO 2013. Abstract 3502. Used without permission.

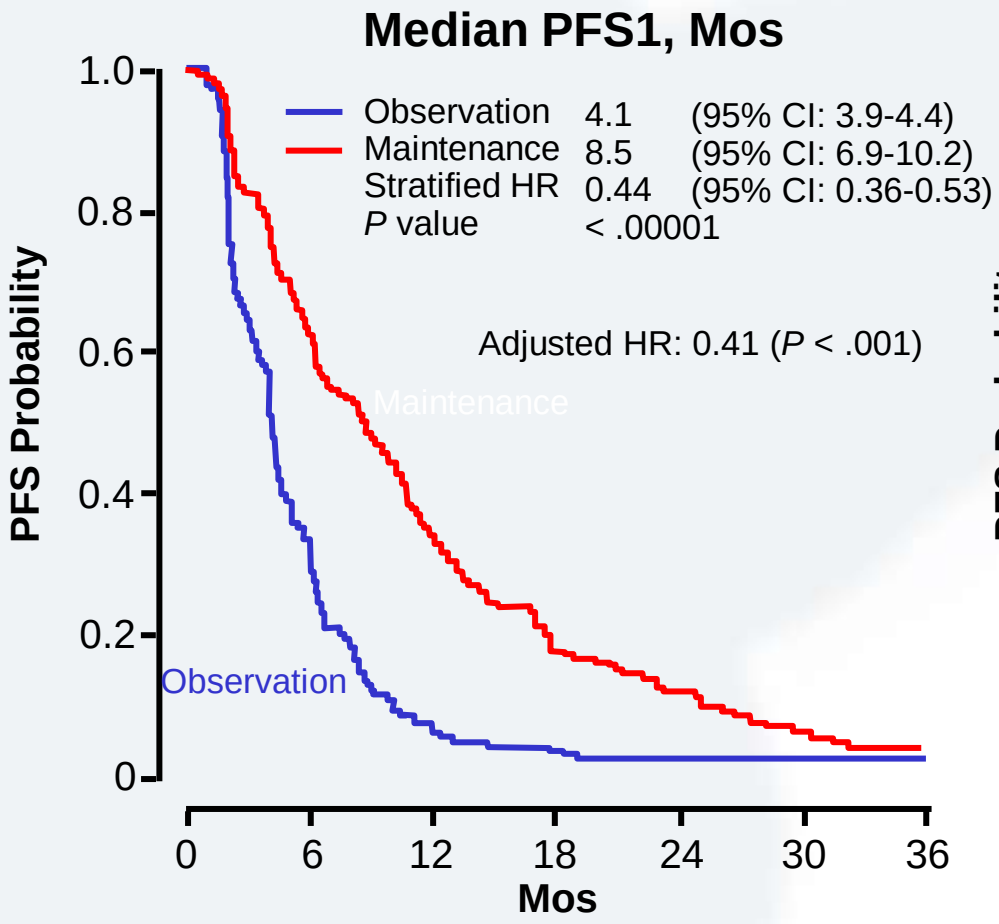
Phase III CAIRO-3: Bevacizumab + CT **maintenance** vs observation

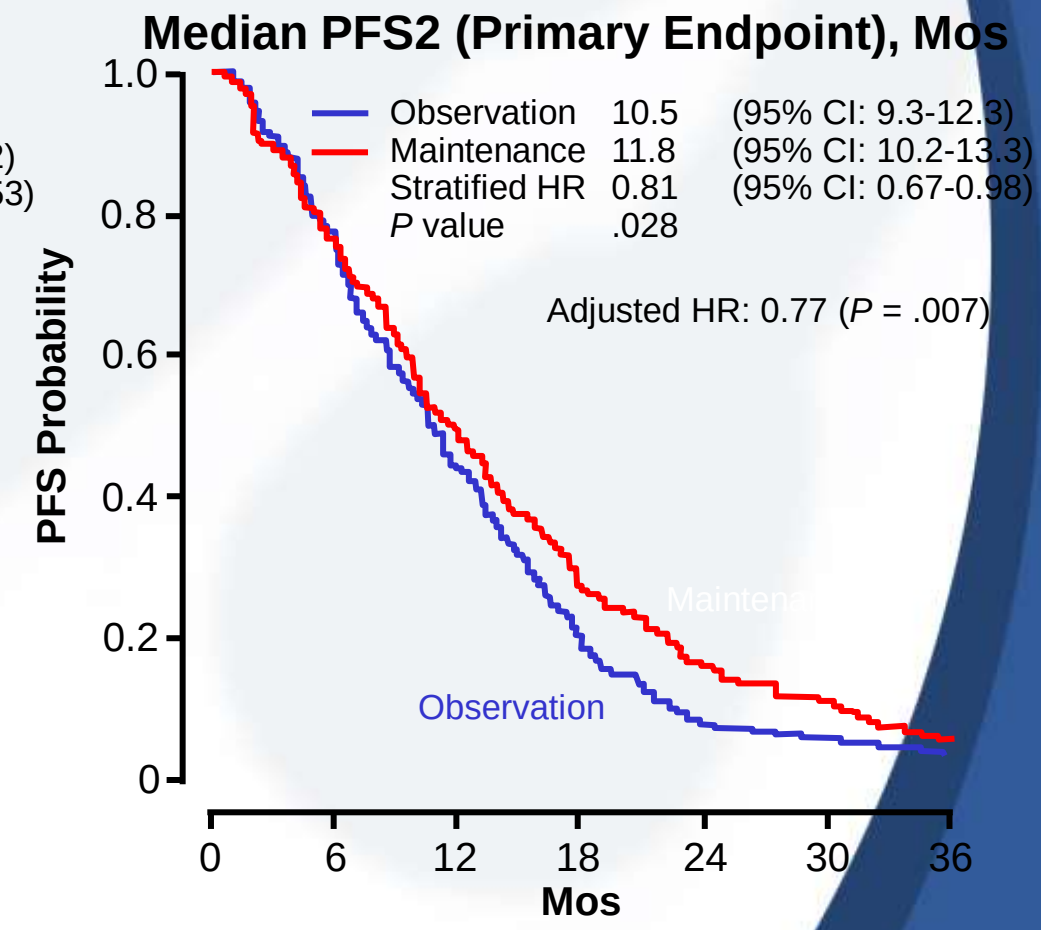


- **Primary endpoint:** PFS2
- **Secondary endpoints:** OS, TTP2 (time to progression or death after PS1)

Koopman M, et al. ASCO 2013 (Abstract No. 3502)

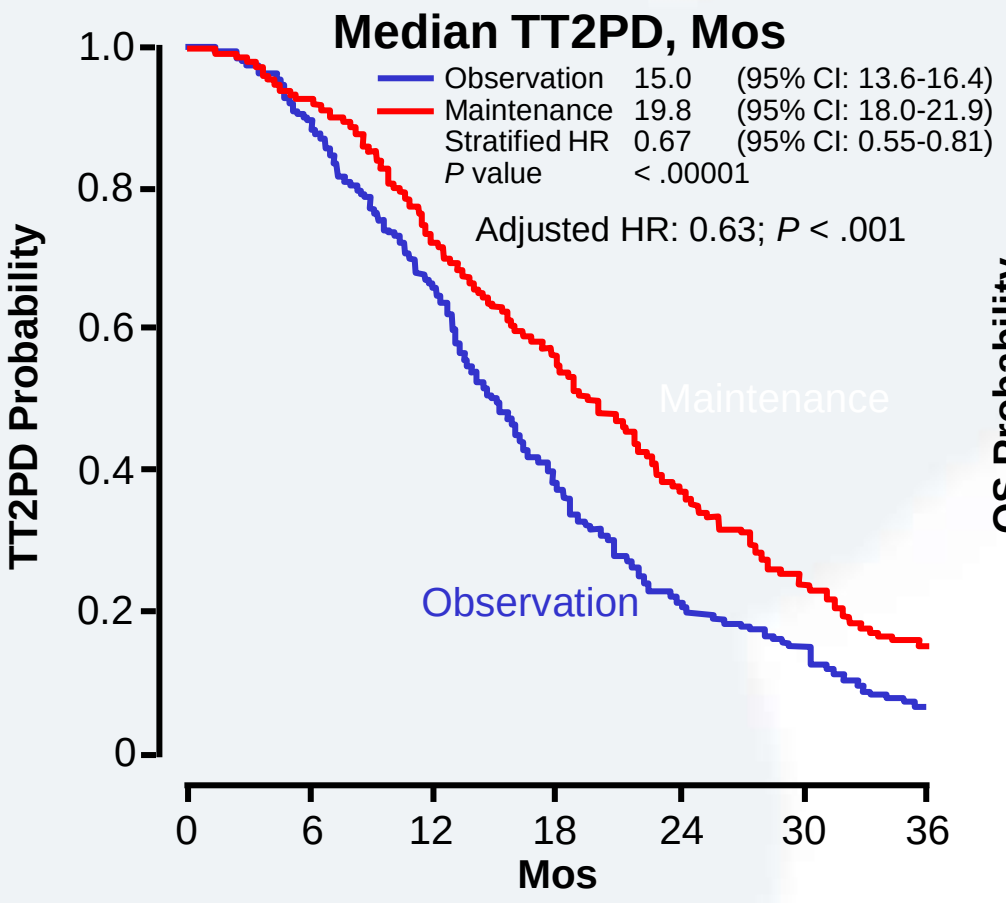
CAIRO-3 PFS tulokset

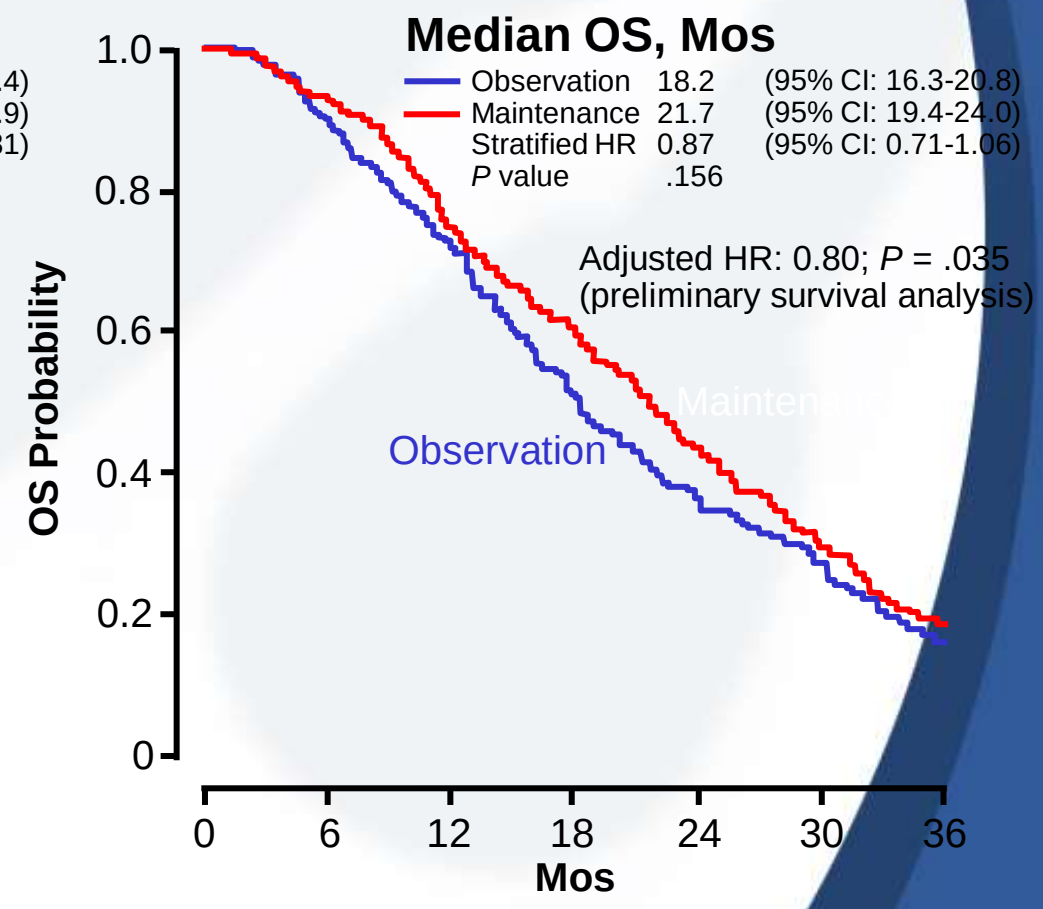




Koopman M, et al. ASCO 2013. Abstract 3502. Used with permission.

CAIRO-3 TT2PD ja OS tulokset





Maintenance tre
6 cycles CAPOX

Koopman M, et al. ASCO 2013. Abstract 3502. Used with permission.

Faasi III CAIRO-3 : Ylläpito kapesitabiini + bevasitsumabi vs seuranta metastasoineessa kolorektaalisyövässä

	Observation	Continued Avastin + Xeloda	Stratified HR (95% CI)	p value	Adjusted HR*	p value
Median PFS2 (months)	10.5	11.8	0.81 (0.67–0.98)	0.028	0.77	0.007
Median OS (months)	18.2	21.7	0.87 (0.71–1.06)	0.156	0.80	0.035
Median PFS1 (months)	4.1	8.5	0.44 (0.36–0.53)	<0.00001	0.41	<0.001
Median TTP2 (months)	15.0	19.8	0.67 (0.55–0.81)	<0.00001	0.63	<0.001

Koopman M, et al. ASCO 2013. Abstract 3502. Used with permission.

Faasi III CAIRO-3 : Ylläpito kapesitabiini + bevasitsumabi vs seuranta metastasoineessa kolorektaalisyövässä

- Ylläpitohoito kapesitabiinilla ja bevasitsumabilla kuuden xelox-b kuurin jälkeen pidentää aikaa taudin etenemiseen

Keskimääräinen PFS1: 8.5 kk ylläpitohoidolla vs 4.1 kk seurannalla

Keskimääräinen PFS2: 11.8 kk ylläpitohoidolla vs 10.5 kk seurannalla

- Ylläpitohoito pidentää aikaa toiseen taudin etenemisvaiheeseen

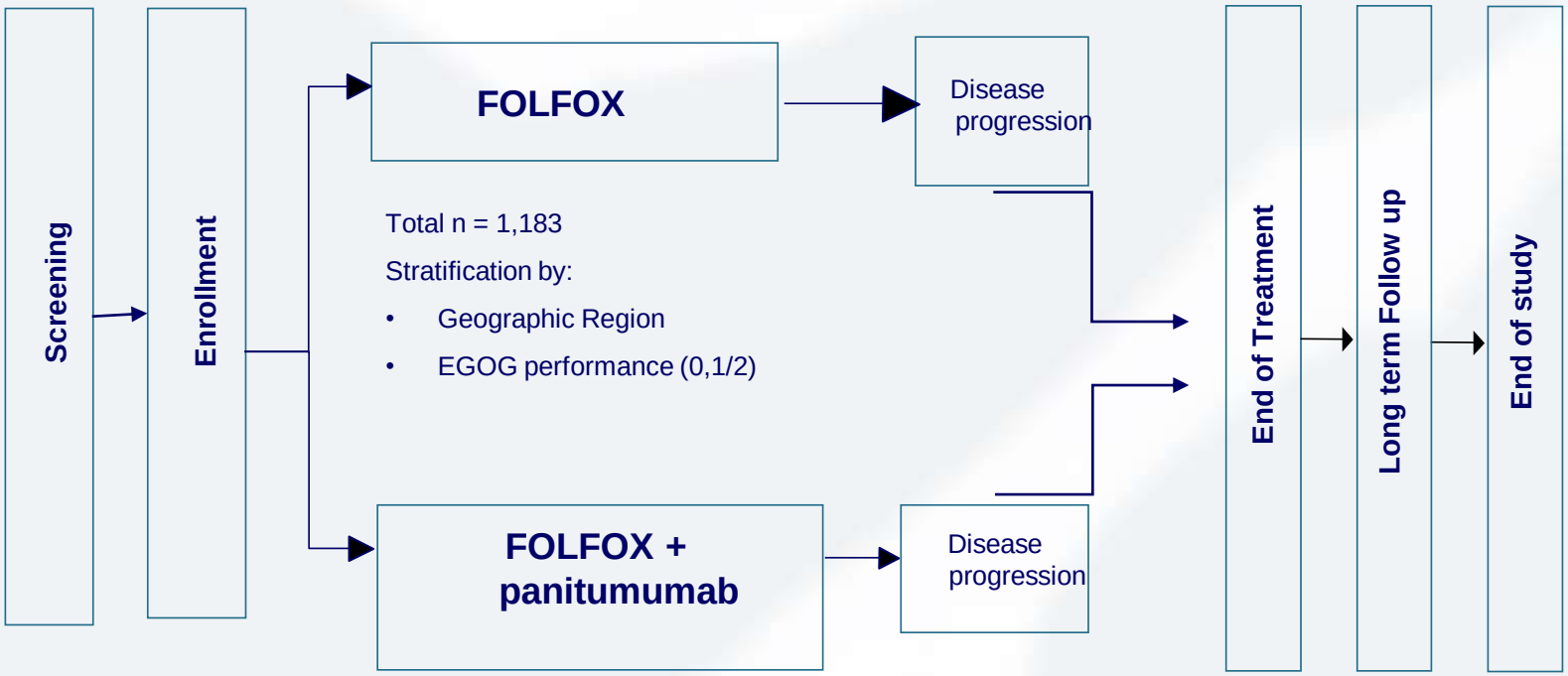
TTP2: 19.8kk ylläpitohoidolla vs 15.0 kk seurannalla

- OS hyöty alustavassa arviossa

OS: 21.7 kk ylläpitohoidolla vs 18.2 kk seurannalla

Koopman M, et al. ASCO 2013. Abstract 3502. Used with permission.

PRIME Study – FOLFOX +/- Panitumumabi ensilinjan metastaattisessa kolorektaalisyövässä



Study Description

A Randomized, Multicenter, Phase 3 Study to Compare the Efficacy of Panitumumab in Combination with Oxaliplatin/ 5-fluorouracil/ leucovorin to the Efficacy of Oxaliplatin/ 5-fluorouracil/ leucovorin Alone in Patients with Previously Untreated Metastatic Colorectal Cancer

Hypothesis

The addition of panitumumab to chemotherapy (FOLFOX) will increase progression-free survival (PFS) compared to chemotherapy (FOLFOX) alone as first-line treatment of mCRC among subjects with wild-type KRAS tumors and subjects with mutant KRAS tumors.

Endpoints

Primary Endpoint:
PFS

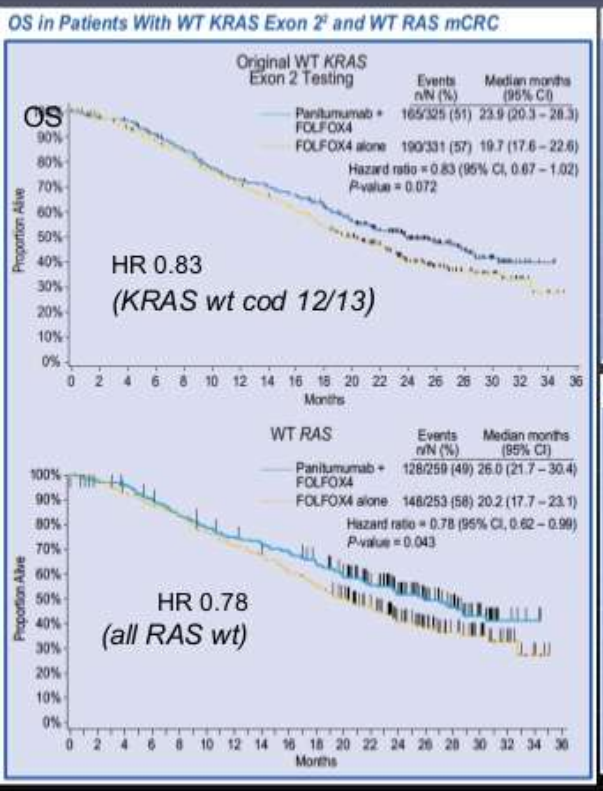
Secondary Endpoints:
OS, ORR, TTP, DOR, Safety

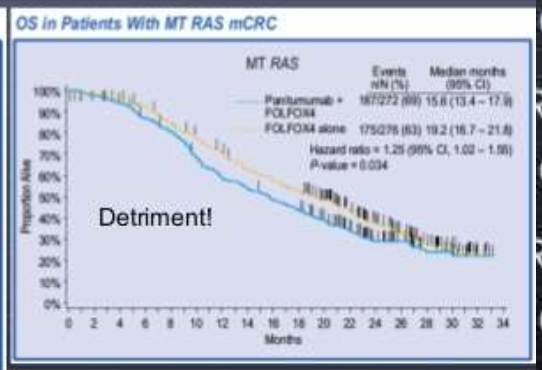
Tertiary/Exploratory Endpoints: TTR, Biomarkers, PRO

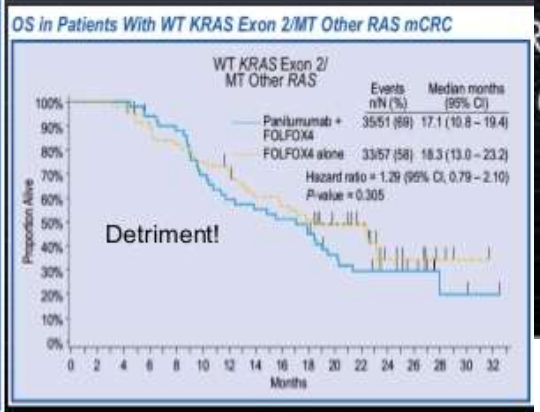
Updated Analysis of PRIME study

RAS and BRAF Status

	Panitumumab + FOLFOX4	FOLFOX4 Alone	Total
KRAS exon 2 (codons 12/13)			
Wild-type	325	331	656
Mutant	221	219	440
Wild-type *KRAS* exon 2 tumors tested for *RAS* and *BRAF*	N = 320	N = 321	N = 641
Wild-type *KRAS* exon 2/mutant other *RAS* – n (%)	51 (16)	57 (18)	108 (17)
KRAS exon 3 (codon 61) – n (%)			
Wild-type	308 (96)	306 (95)	614 (96)
Mutant	10 (3)	14 (4)	24 (4)
Failure	2 (1)	1 (0)	3 (0)
KRAS exon 4 (codons 117/146) – n (%)			
Wild-type	288 (90)	296 (92)	584 (91)







Oliner et al., ASCO 2013

KRAS exon 2 codon 12/13	**40%**
KRAS exon 3 codon 61	4%
KRAS exon 4 don 117/146	6%
RAS exon 2 don 12/13	3%
RAS exon 3 don 61	4%
RAF exon 15 don 600	8%

17%

Oliner et al., ASCO 2013

PRIME *RAS/RAF* analyysi

	Panitumumabi+ FOLFOX4 (kk) mediaani (95% CI)	FOLFOX4 (kk) mediaani (95% CI)	Ero (kk)	
Villin tyypin RAS				
PFS	**10.1** (9.3–12.0)	**7,9** (7.2–9.3)	**2,2**	0,72 (0,58-0,90)
OS	**26,0** (21,7-30,4)	**20.2** (17,7–23.1)	**5,8**	0,78 (0,62-0,99)
RAS mutaatio				
PFS	**7,3** (6,3–7,9)	**8,7** (7,6–9,4)	**-1,4**	1,31 (1,07-1,60)
OS	**15,6** (13,4-17,9)	**19.2** (16,7-21,8)	**-3,6**	1,25 (1,02-1,55)

Kolorektaalisyöpä, biologiset lääkkeet

- EGFR vasta-aineiden teho rajoittuu potilaisiin joilla on RAS villin tyypin tuumori

- EGFR vasta-aineineila hoitotulosta huonontava vaikutus RAS mutatoituneissa tuumoreissa

- Bevasitsumabin ja EGFR vasta aineen yhdistelmää (setuksimabi/ panitumumabi) ei tulisi käyttää hoidossa

Faasi III FIRE-3 tutkimus: ensilinjan FOLFIRI + joko setuksimabi tai bevasitsumabi *KRAS*-WT mCRC

mCRC
ja *KRAS* WT,
ECOG PS 0-2
(N = 592)

→ **FOLFIRI +**
Cetuximab 400 mg/m^2 loading then 250 mg/m^2 q1w
(n = 297)

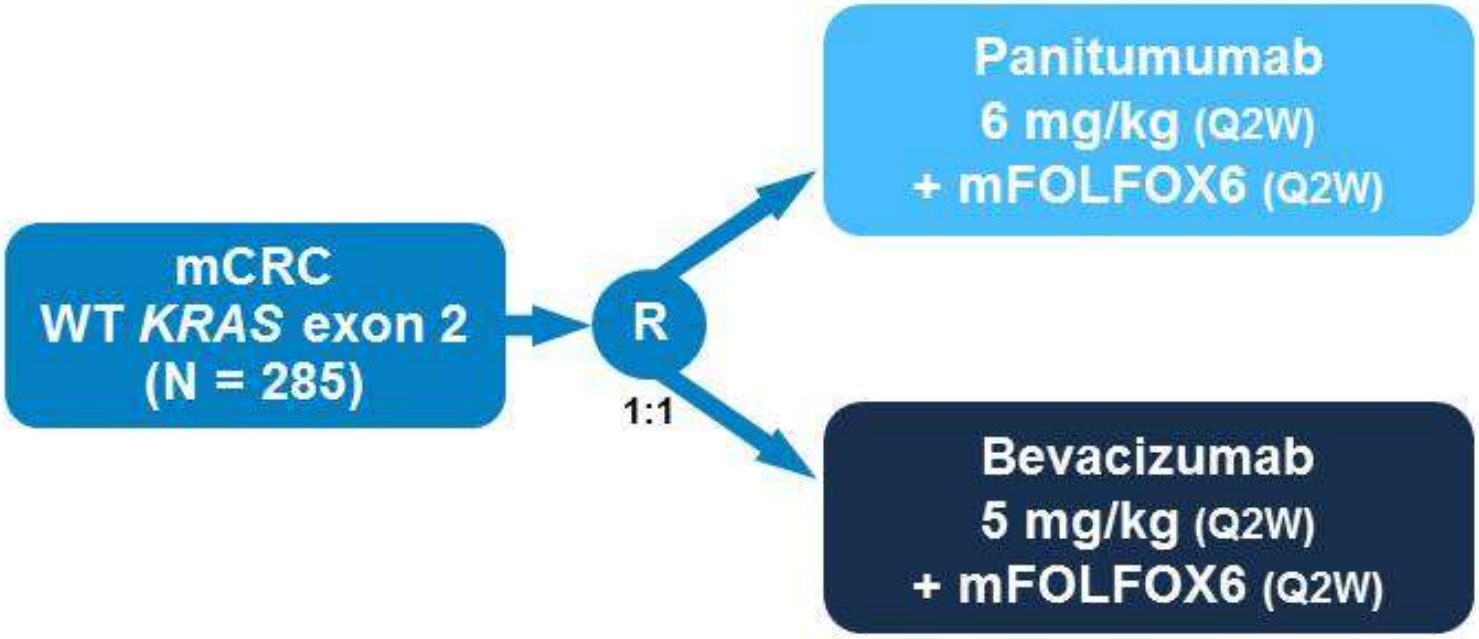
→ **FOLFIRI +**
Bevacizumab 5 mg/kg q2w
(n = 295)

- Ensisijainen päätetapahtuma: ORR
- Toissijaiset päätetapahtumat: PFS, OS, TTF, tuumorin pieneneminen leikattavuus, turvallisuus

Stintzing S, et al. ASCO 2013. Abstract LBA3506. Used without permission.

PEAK study
1st-line mFOLFOX6 + panitumumab or bevacizumab

Open label Phase 2 study



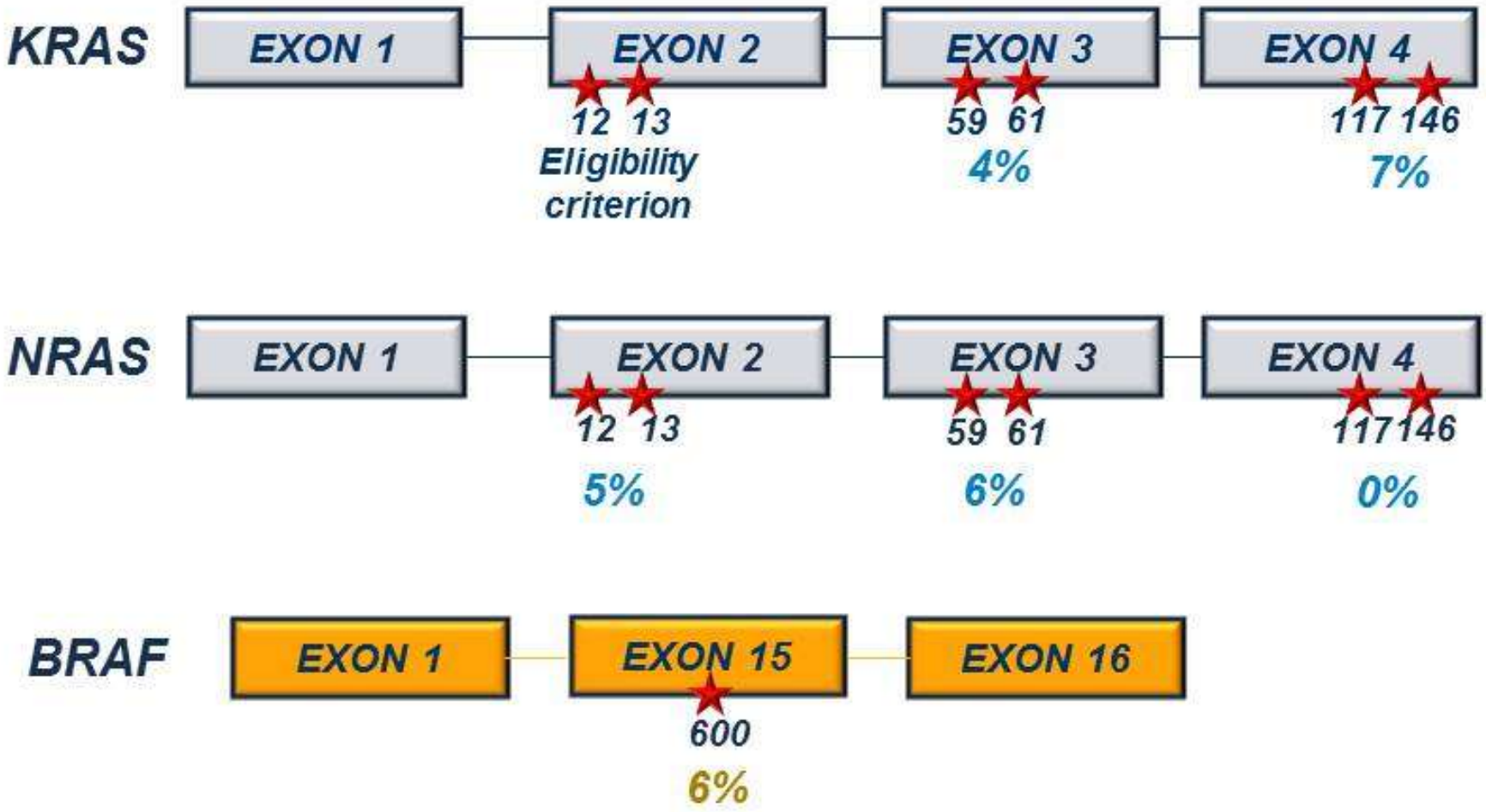
Tumour assessment Q8W
Treatment administered until progression, death or withdrawal from study

- Study endpoints: PFS (1°)†, OS, ORR, resection rate, safety, exploratory biomarker analysis

Schwartzberg L, et al. J Clin Oncol 2013;31 (suppl; abstract 3631 and poster); Protocol ID: 20070509; ClinicalTrials.gov identifier: NCT00819780.

†No formal hypothesis testing planned.
OS, overall survival; ORR, objective response rate; mFOLFOX6, modified FOLFOX6.

PEAK study
KRAS, *NRAS* and *BRAF* mutation hotspots



Prevalence of mutations in PEAK tumour samples within the WT *KRAS* exon 2 subset (80% ascertainment*);
*Ascertainment defined as percentage of patients with a known codon sequence result at all listed positions above.

Schwartzberg L, et al. J Clin Oncol 2013;31 (suppl; abstract 3631 and poster).

Faasi III FIRE-3 tutkimus: ensilinjan FOLFIRI + joko setuksimabi tai bevasitsumabi *KRAS*-WT mCRC: ORR

RECIST, n (%)	FOLFIRI + Cetuximab (n = 297)	FOLFIRI + Bevacizumab (n = 295)
CR	13 (4.4)*	4 (1.4)*
PR	171 (57.6)	167 (56.6)
SD	53 (17.5)*	85 (28.8)*
PD	21 (7.1)	16 (5.4)
Not evaluable	39 (13.1)	23 (7.8)

*Significant differences in response.

Stintzing S, et al. ASCO 2013. Abstract LBA3506. Used without permission.

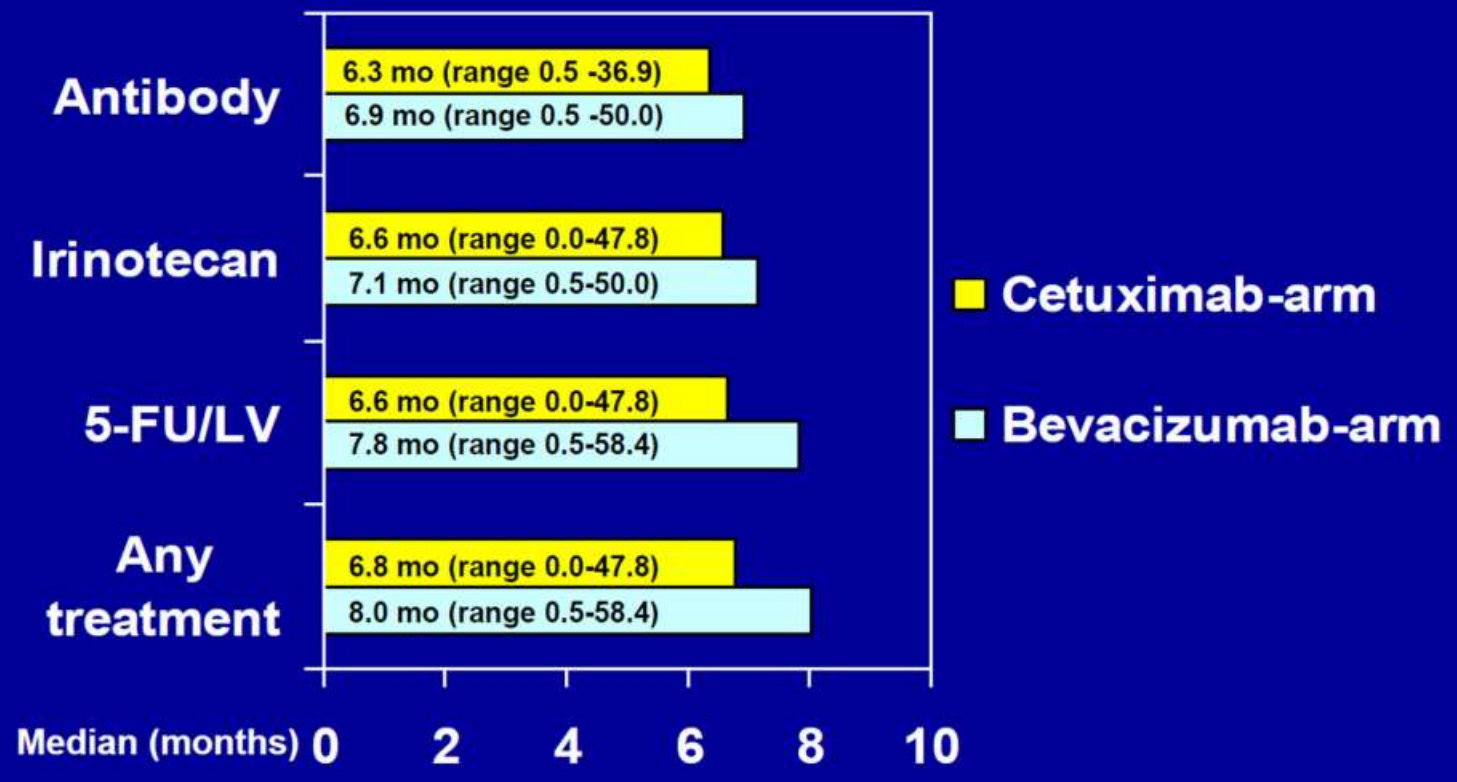
FIRE-3 trial
Summary of efficacy data in WT *KRAS* mCRC

	FOLFIRI + cetuximab (n = 297)	FOLFIRI + bevacizumab (n = 295)
ORR	62%	57%
Odds ratio	1.249	
Median PFS, months	10.3	10.4
Δ Median PFS, months	0.1	
Hazard ratio (P-value)	1.04 (P = 0.69)	
Median OS, months	28.8	25.0
Δ Median OS, months	3.8	
Hazard ratio (P-value)	0.77 (P = 0.0164)	

Heinemann V, et al. J Clin Oncol 2013;31 (suppl; abstract LBA3506).

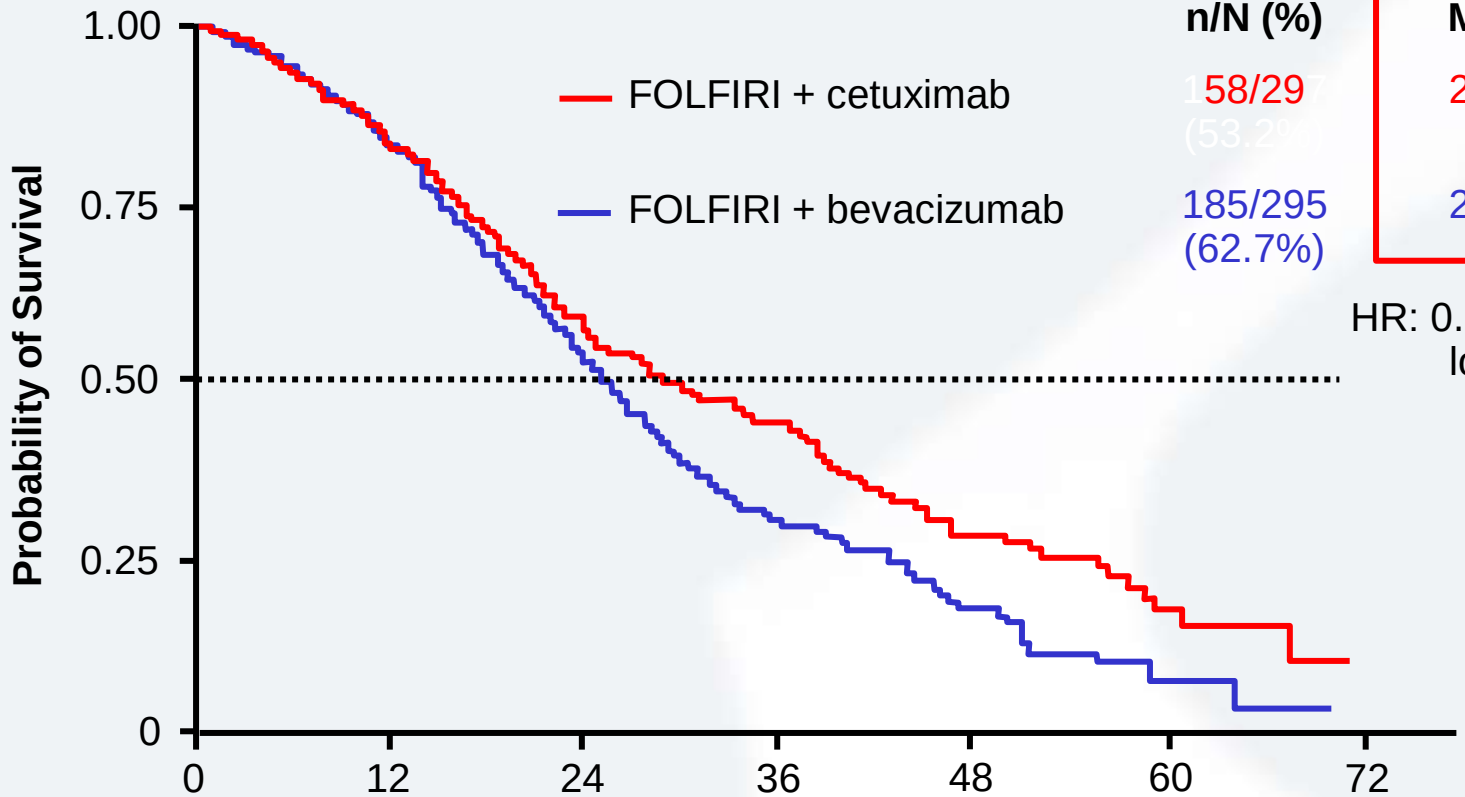
ORR, objective response rate.

Treatment duration with 1st-line substances



Including treatment holidays, de- and re-escalations

FIRE-3 Trial of First-line FOLFIRI + Either Cetux or Bev in *KRAS*-WT mCRC: OS



	Events, n/N (%)	Median Mos	95% CI
FOLFIRI + cetuximab	158/297 (53.2%)	28.7	24.0-36.6
FOLFIRI + bevacizumab	185/295 (62.7%)	25.0	22.7-27.6

HR: 0.77 (95% CI: 0.62-0.96; log-rank *P* = .017)

Pts at Risk, n

297	218	111	60	29	9
295	214	111	47	18	2

Stintzing S, et al. ASCO 2013. Abstract LBA3506. Used with permission.

Faasi III FIRE-3 tutkimus: ensilinjan FOLFIRI + joko setuksimabi tai bevasitsumabi *KRAS*-WT mCRC: toisen vaiheen hoito

Second-line Regimen, %	FOLFIRI + Cetuximab (n = 297)	FOLFIRI + Bevacizumab (n = 295)
Any	65.7	61.7*
Bevacizumab	48.2	17.6
Anti-EGFR	14.4	42.9

*P = .347

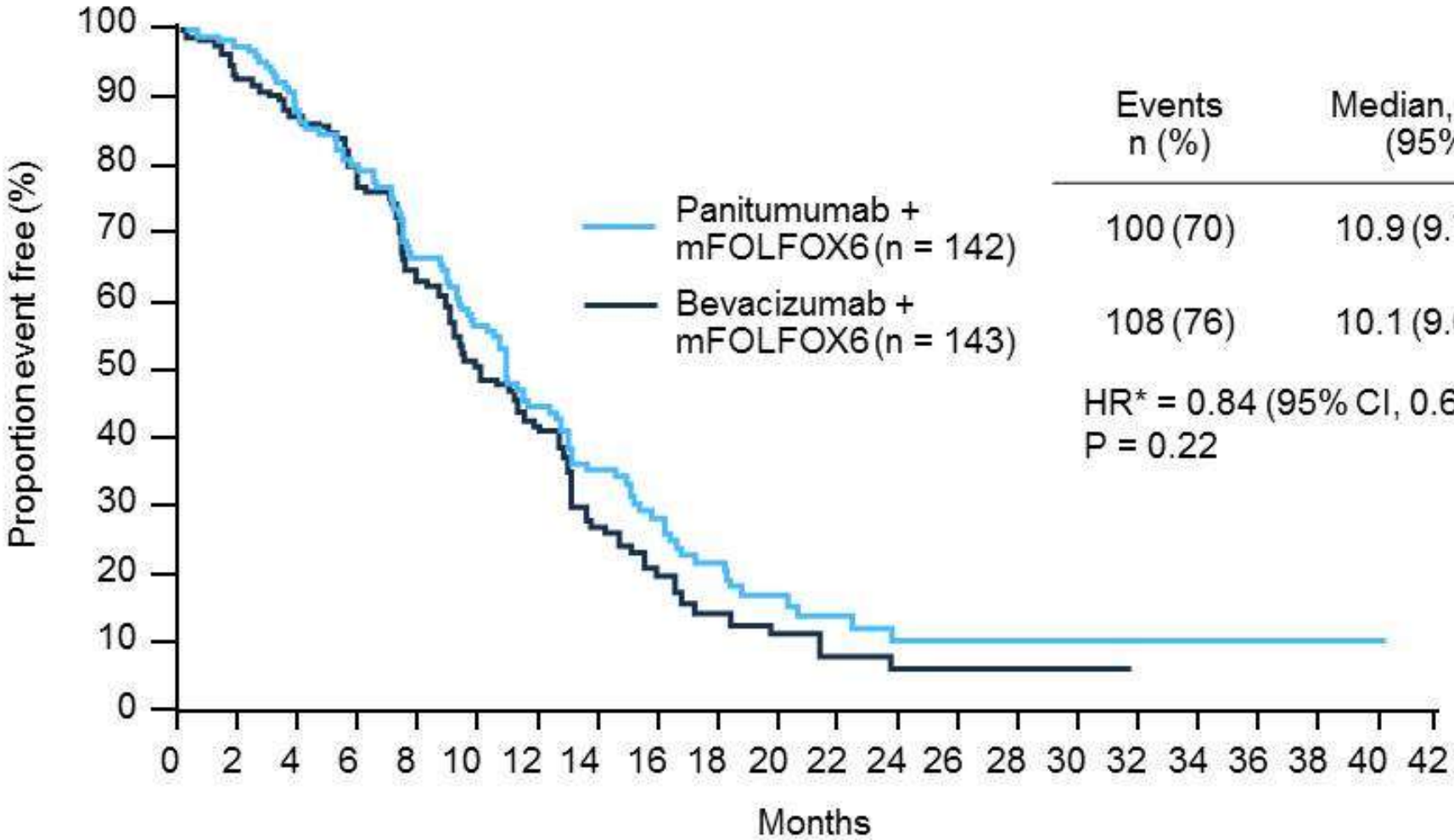
Stintzing S, et al. ASCO 2013. Abstract LBA3506. Used without permission.

2nd-line treatment

	FOLFIRI + Cetuximab N= 297	FOLFIRI + Bevacizumab N= 295
Alive after 1st-line therapy	87.5% (260/297)	84.7% (250/295)
Any 2nd-line therapy	78.5% (204/260)	76.4% (191/250)
2nd-line substances, %	n=204 (100)	n=191 (100)
Fluoropyrimidine %	91.7	85.3
Oxaliplatin %	63.7	62.8
Irinotecan %	15.7	15.7
Bevacizumab %	46.6	17.3
Anti-EGFR mAB %	15.2	41.4

Treatment with a substance not being part of 1st-line therapy

PEAK study biomarker analysis
PFS in WT *KRAS* exon 2 mCRC



	Events n (%)	Median, months (95% CI)
Panitumumab + mFOLFOX6 (n = 142)	100 (70)	10.9 (9.7–12.8)
Bevacizumab + mFOLFOX6 (n = 143)	108 (76)	10.1 (9.0–12.0)

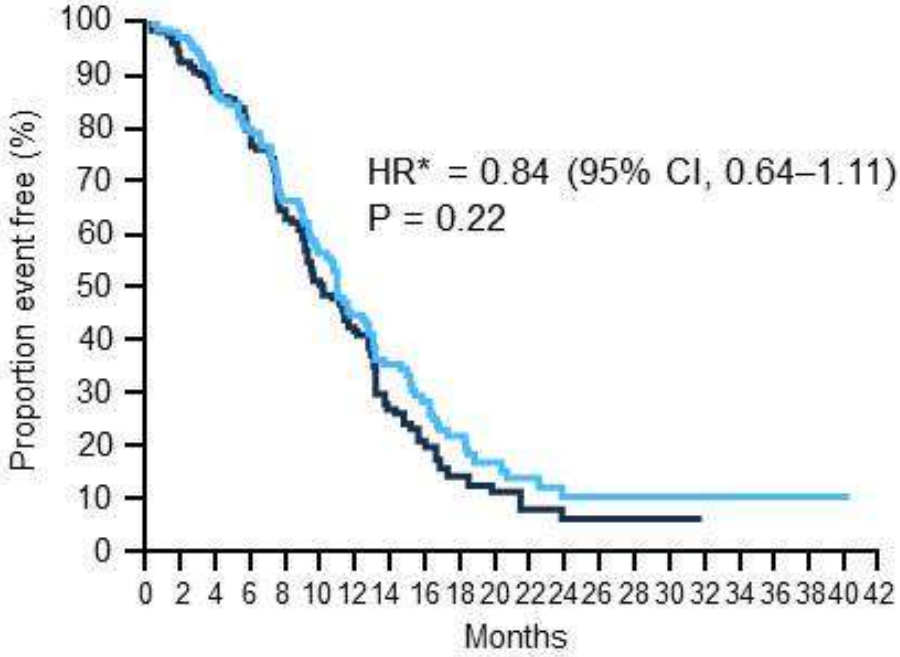
HR* = 0.84 (95% CI, 0.64–1.11)
P = 0.22

Schwartzberg L, et al. J Clin Oncol 2013;31 (suppl; abstract 3631 and poster).

*Stratified Cox proportional hazards model; Data cutoff 3 Jan 2013.

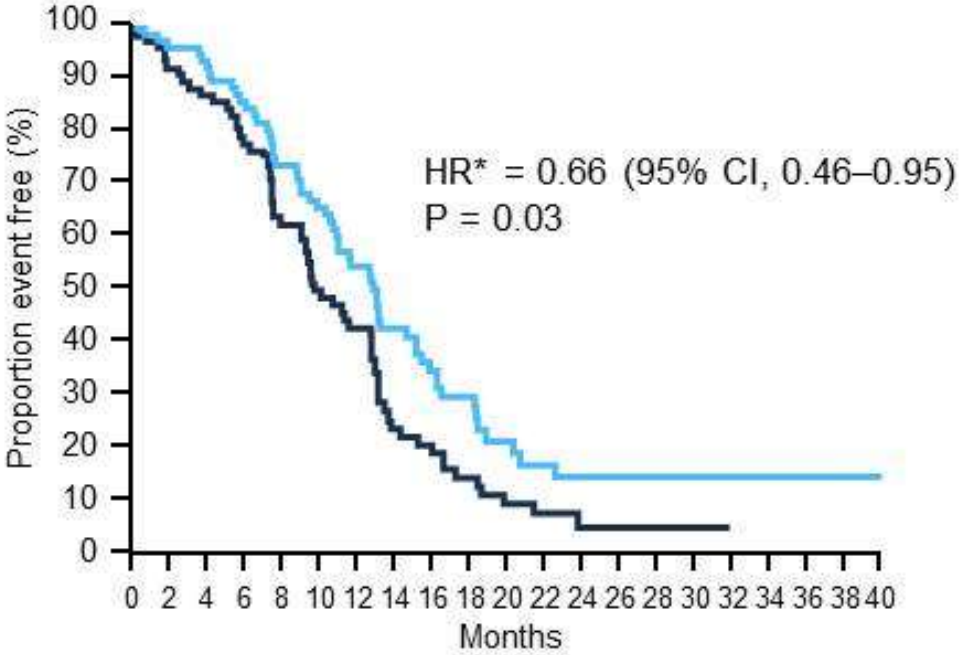
PEAK study biomarker analysis
PFS in WT *KRAS* exon 2 and WT *RAS* mCRC

PEAK (mFOLFOX6)
WT *KRAS* exon 2 (ITT set)



	Events n (%)	Median (95% CI) months
Panitumumab + mFOLFOX6 (n = 142)	100 (70)	10.9 (9.7–12.8)
Bevacizumab + mFOLFOX6 (n = 143)	108 (76)	10.1 (9.0–12.0)

PEAK (mFOLFOX6)
WT *RAS* (exons 2, 3, 4 of *KRAS/NRAS*)



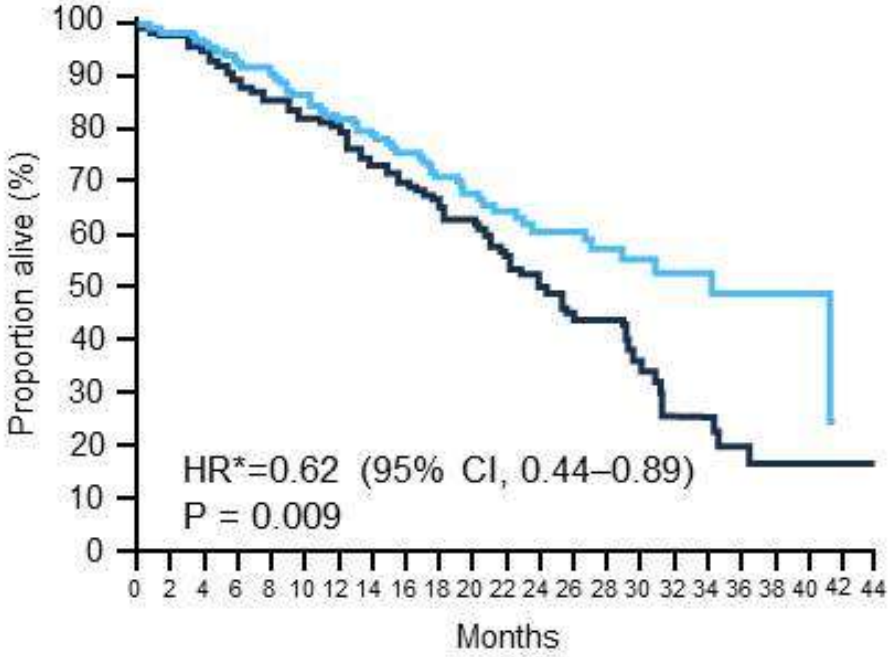
	Events n (%)	Median (95% CI) months
Panitumumab + mFOLFOX6 (n = 88)	57 (65)	13.0 (10.9–15.1)
Bevacizumab + mFOLFOX6 (n = 82)	66 (80)	10.1 (9.0–12.7)

Schwartzberg L, et al. J Clin Oncol 2013;31 (suppl; abstract 3631 and poster).

*Stratified Cox proportional hazards model; Data cutoff 3 Jan 2013.

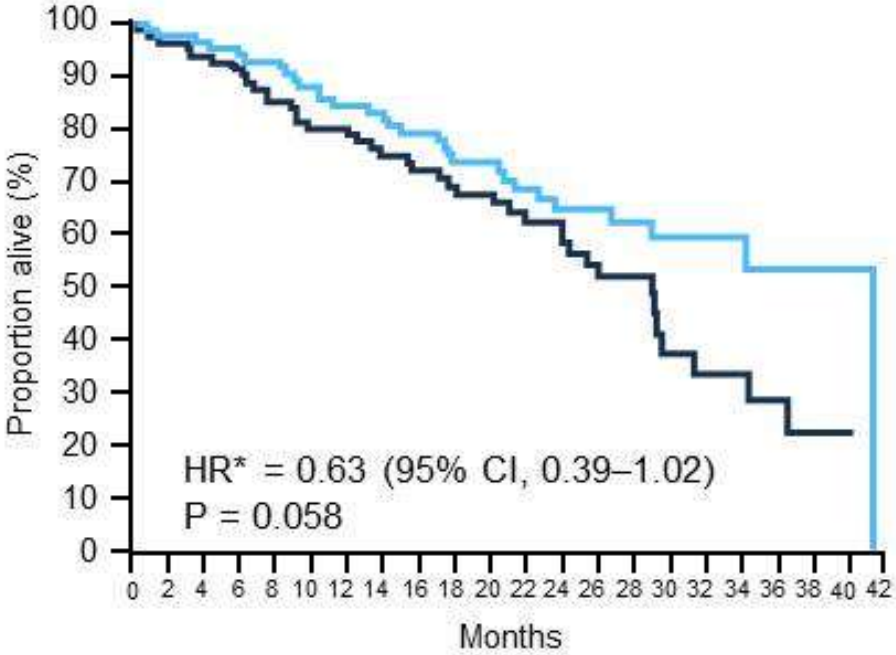
PEAK study biomarker analysis
OS in WT *KRAS* exon 2 and WT *RAS* mCRC

PEAK (mFOLFOX6)
WT *KRAS* exon 2 (ITT set)



	Events n (%)	Median (95% CI) months
Panitumumab + mFOLFOX6 (n = 142)	52 (37)	34.2 (26.6–NR)
Bevacizumab + mFOLFOX6 (n = 143)	78 (55)	24.3 (21.0–29.2)

PEAK (mFOLFOX6)
WT *RAS* (exons 2, 3, 4 of *KRAS/NRAS*)



	Events n (%)	Median (95% CI) months
Panitumumab + mFOLFOX6 (n = 88)	30 (34)	41.3 (28.8–41.3)
Bevacizumab + mFOLFOX6 (n = 82)	40 (49)	28.9 (23.9–31.3)

Data cutoff 3 Jan 2013.

Schwartzberg L, et al. J Clin Oncol 2013;31 (suppl; abstract 3631 and poster).

*Stratified Cox proportional hazards model; NR, not reached

PEAK study biomarker analysis
Post progression treatment

WT *RAS* mCRC	Panitumumab + mFOLFOX6 (n = 88)	Bevacizumab + mFOLFOX6 (n = 82)
Patients who received **anti-EGFR** monoclonal antibody therapy after the protocol treatment phase		
n (%)	9 (10)	23 (28)
Median*, months	14.7	14.5
Patients who received **anti-VEGF** therapy after the protocol treatment phase		
n (%)	27 (31)	25 (30)
Median*, months	12.9	8.4

Schwartzberg L, et al. J Clin Oncol 2013;31 (suppl; abstract 3631 and poster).

*Median calculated from randomisation date
Data cutoff 30 May 2012.

Raxo tutkimus

Väestöpohjainen tutkimus jossa selvitetään levinneeseen suolistosyöpään sairastuneiden taudin kliinistä käyttäytymistä, etäpesäkirurgian mahdollisuutta ja elinaikaa.

Ensisijainen tavoite:

arvioida etäpesäkkeistä kolorektaalisyövän kliinistä käyttäytymistä ja levinnyttä suolistosyöpää sairastavien potilaiden yleistä soveltuvuutta leikkaushoitoon, leikkauksenjälkeistä sairastuvuutta ja etäpesäpoiston hoitotuloksia

Toissijaiset tavoitteet:

arvioida vasteen saaneiden osuutta, aikaa hoidon päättymiseen, aikaa ilman syövän etenemistä ja kokonaiselossaoloaikaa

arvioida radiologisesti kasvaimen tiheyttä ja rakennetta ja verrata vaihtoehtoista radiologista vastearviointia kiinteitä kasvaimia koskeviin RECIST-vastekriteereihin

biomerkkiainemääritykset plasmasta ja seerumista sekä DNA:sta sellaiset geenimääritykset, jotka voivat lisätä tietoa hoidon tehosta, turvallisuudesta sekä tuumorin kasvusta

Tutkimukseen rekrytoidaan yhteensä 1 000 potilasta

Kaikki Suomen sairaalat, joissa hoidetaan kolorektaalisyöpää (noin 20)

Tutkimukseenottoperusteet
potilaat, joiden kolorektaalisyöpädiagnoosi on varmennettu histologisesti ja joille on tarkoitus aloittaa ensilinjan solunsalpaajahoito etäpesäkkeisen syövän hoitoon tai jotka saavat parhaillaan tai ovat saaneet ensilinjan solunsalpaajahoitoa etäpesäkkeisen syövän hoitoon
18 vuotta täyttäneet potilaat
etäpesäkkeinen syöpä tai paikallisesti edennyt syöpä joka ei ole leikattavissa.
ennen tutkimusta annettu, hyvän kliinisen tutkimustavan (ICH-GCP) ja paikallisten määräysten mukainen tietoon perustuva kirjallinen suostumus (potilas allekirjoittaa eettisen toimikunnan hyväksymän tiedotteen ja suostumuksen)

Kahvitauon ja näyttelyn välissä on vain tämä dia

Kiitoksia mielenkiinnosta

Kysymyksiä ???