Präzisionsonkologie im perioperativen Setting: Jetzt und in Zukunft

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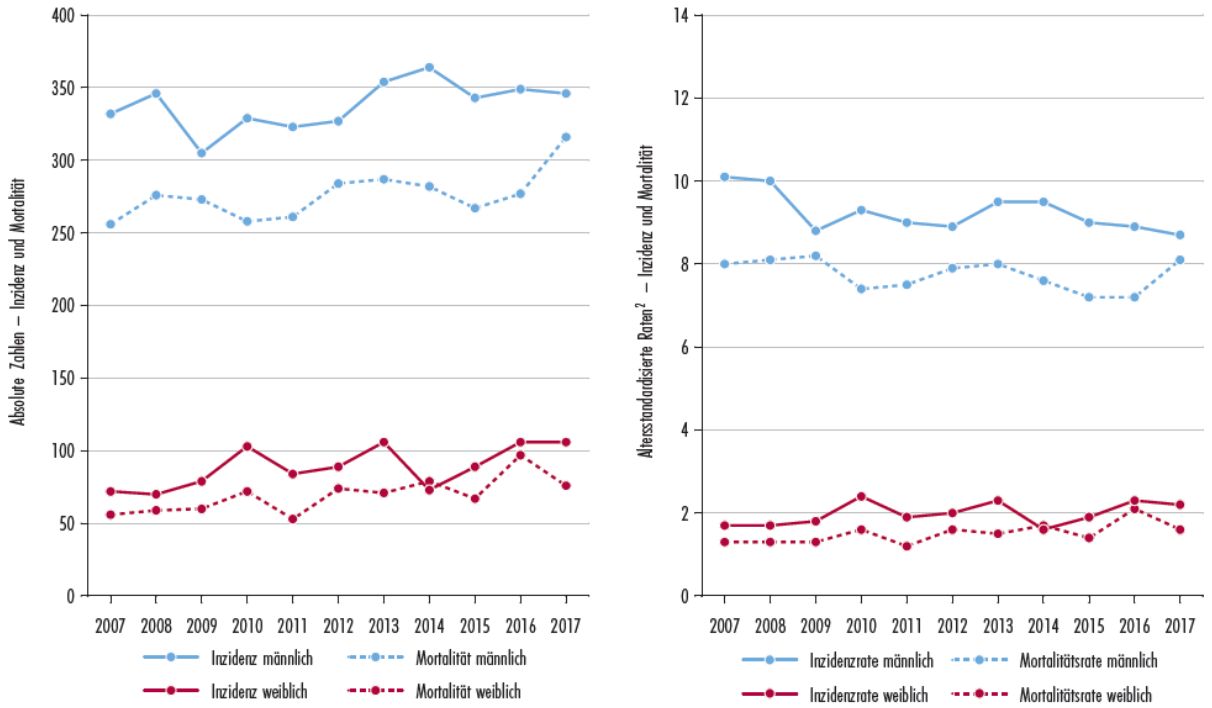
DKG KREBSGESELLSCHAFT
Zertifiziertes Onkologisches Zentrum

EUROPEAN CANCER CENTRES | Zertifiziertes Onkologisches Zentrum

KABEG KLINIKUM KLAGENFURT AM WÖRTHERSEE

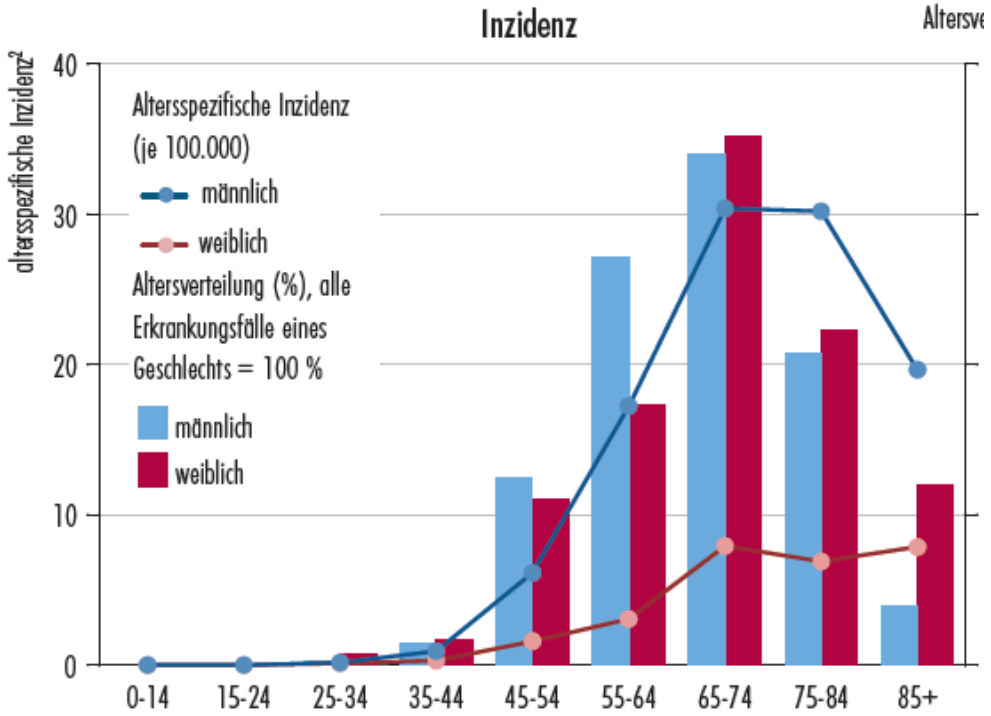
Epidemiologie Ösophaguskarzinom Österreich

Entwicklung der bösartigen Neubildungen der Speiseröhre[1], Österreich ab 2007



Q: STATISTIK AUSTRIA, Österreichisches Krebsregister (Stand 09.12.2019) und Todesursachenstatistik. – [1] ICD10: C15.

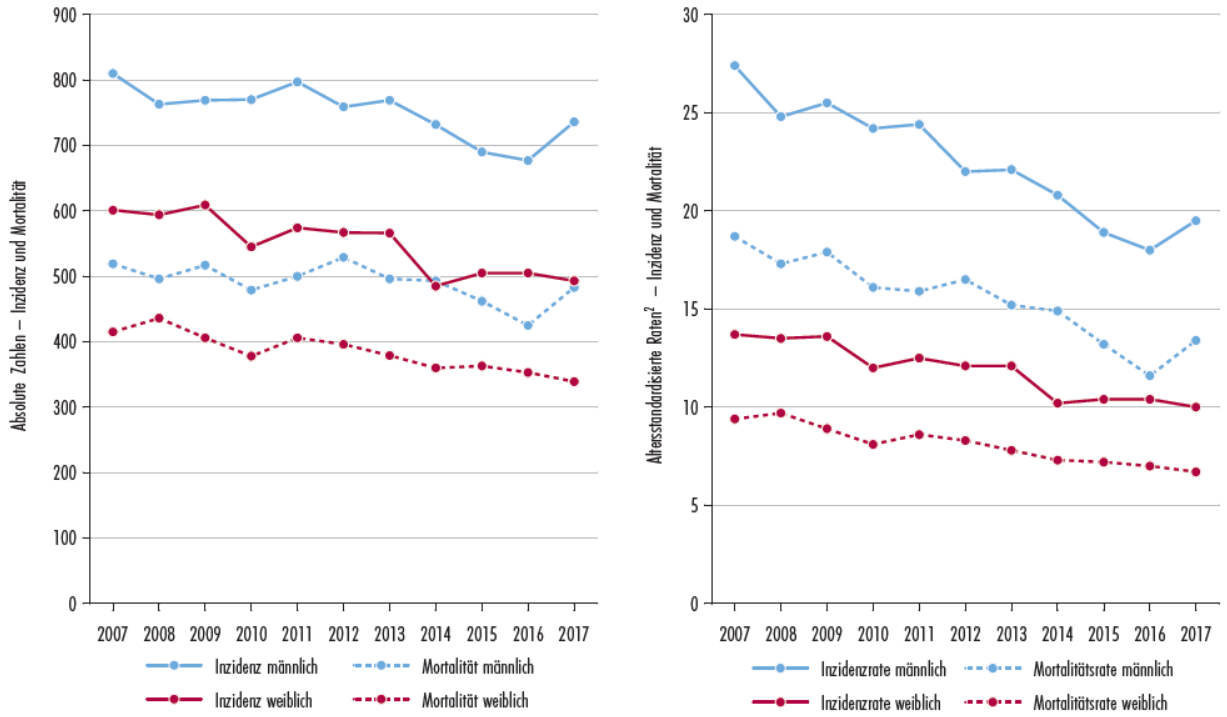
Altersverteilung und altersspezifische Inzidenz bzw. Mortalität der bösartigen Neubildungen der Speiseröhre[1], 2015-2017



Statistik Austria. Österreichisches Krebsregister (Stand 09.12.2019) und Todesursachenstatistik

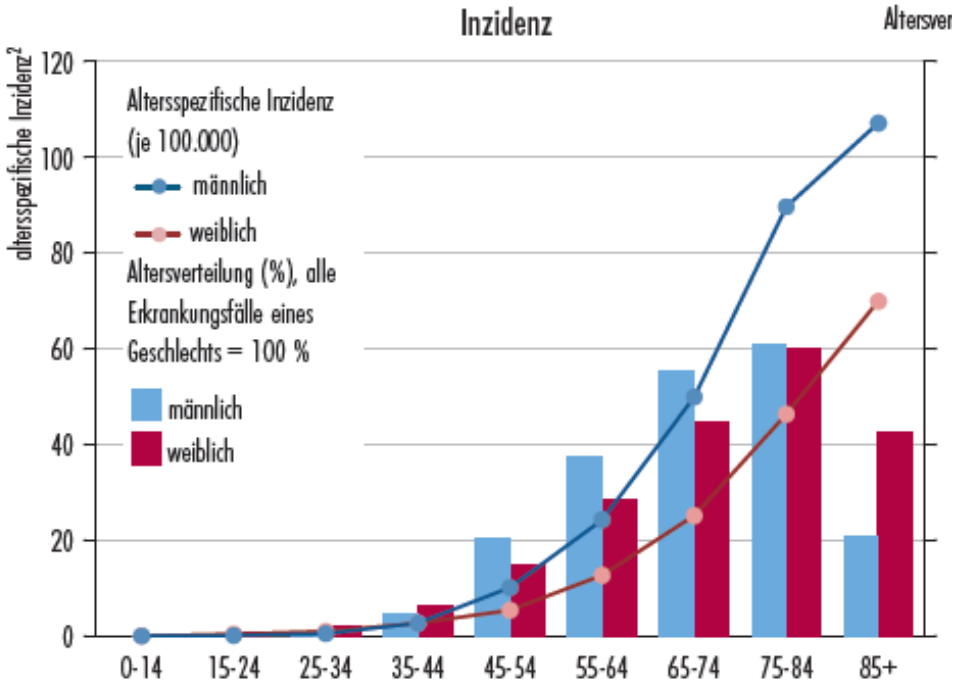
Epidemiologie Magenkarzinom Österreich

Entwicklung der bösartigen Neubildungen des Magens[1], Österreich ab 2007



Q: STATISTIK AUSTRIA, Österreichisches Krebsregister (Stand 09.12.2019) und Todesursachenstatistik. – [1] ICD10: C16. – [2] Jeweils auf 100.000 Männer/Frauen, Europäische Standardbevölkerung 2013.

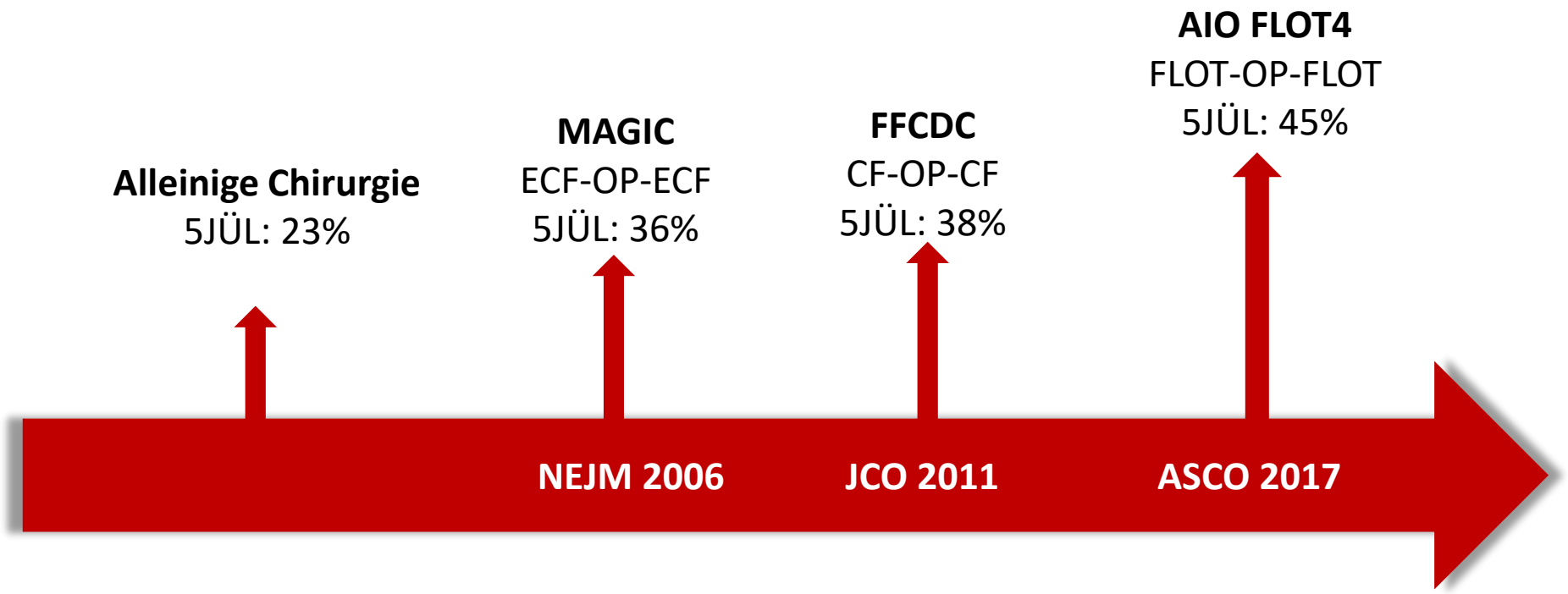
Altersverteilung und altersspezifische Inzidenz bzw. Mortalität der bösartigen Neubildungen des Magens[1], 2015-2017



Statistik Austria. Österreichisches Krebsergister (Stand 09.12.2019) und Todesursachenstatistik

Präzisionsonkologie perioperativ: Jetzt und in Zukunft

Entwicklung der Perioperativen Therapie über die Zeit



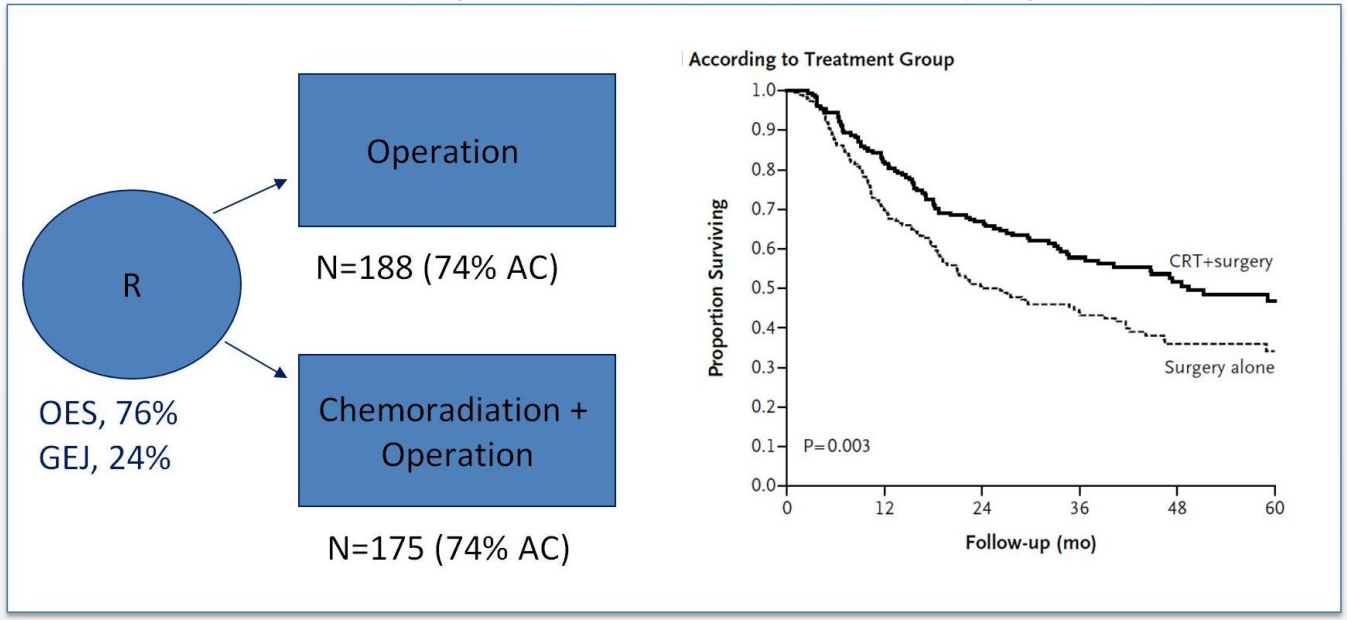
Präzisionsonkologie perioperativ: Jetzt und in Zukunft

Entwicklung der Perioperativen Therapie über die Zeit

CROSS

Preoperative Chemoradiotherapy for Esophageal or Junctional Cancer

P. van Hagen, M.C.C.M. Hulshof, J.J.B. van Lanschot, E.W. Steyerberg,



- Paclitaxel 50mg/m2 + Carboplatin AUC2 d1,8,15,22,29
- Radiotherapie 23x1.8 Gy (41 Gy)

Präzisionsonkologie perioperativ: Jetzt und in Zukunft

ESMO GOOD SCIENCE BETTER MEDICINE BEST PRACTICE

ANNALS OF ONCOLOGY driving innovation in oncology

SPECIAL ARTICLE

Gastric cancer: ESMO Clinical Practice Guideline for diagnosis, treatment and follow-up☆

F. Lordick[1], F. Carneiro[2,3,4], S. Cascinu[5], T. Fleitas[6], K. Haustermans[7], G. Piessen[8,9,10,11], A. Vogel[12] & E. C. Smyth[13], on behalf of the ESMO Guidelines Committee*

Recommendations

- Diagnosis should be made from multiple (5-8) endoscopic biopsies to guarantee an adequate representation of the tumour [IV, B].
- The histological diagnosis should be reported according to WHO criteria [V, B].
- HER2 expression by IHC and/or amplification by *in situ* hybridisation [I, A; ESCAT score: I-A], PD-L1 by IHC according to CPS [I, A] and MSI-H/dMMR [II, A; ESCAT score: I-B] are validated predictive biomarkers for drug therapy.

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ESMO GOOD SCIENCE BETTER MEDICINE BEST PRACTICE

ANNALS OF ONCOLOGY driving innovation in oncology

REVIEW ARTICLE

Recommendations for the use of next-generation sequencing (NGS) for patients with metastatic cancers: a report from the ESMO Precision Medicine Working Group

Mosele et al. Ann Oncol 2020 31(11):1491-1505

Table 2. Summary recommendations

Tumour types	General recommendations for daily practice	Recommendation for clinical research centres	Special considerations for patients
Gastric cancers	No current indication for tumour multigene NGS		

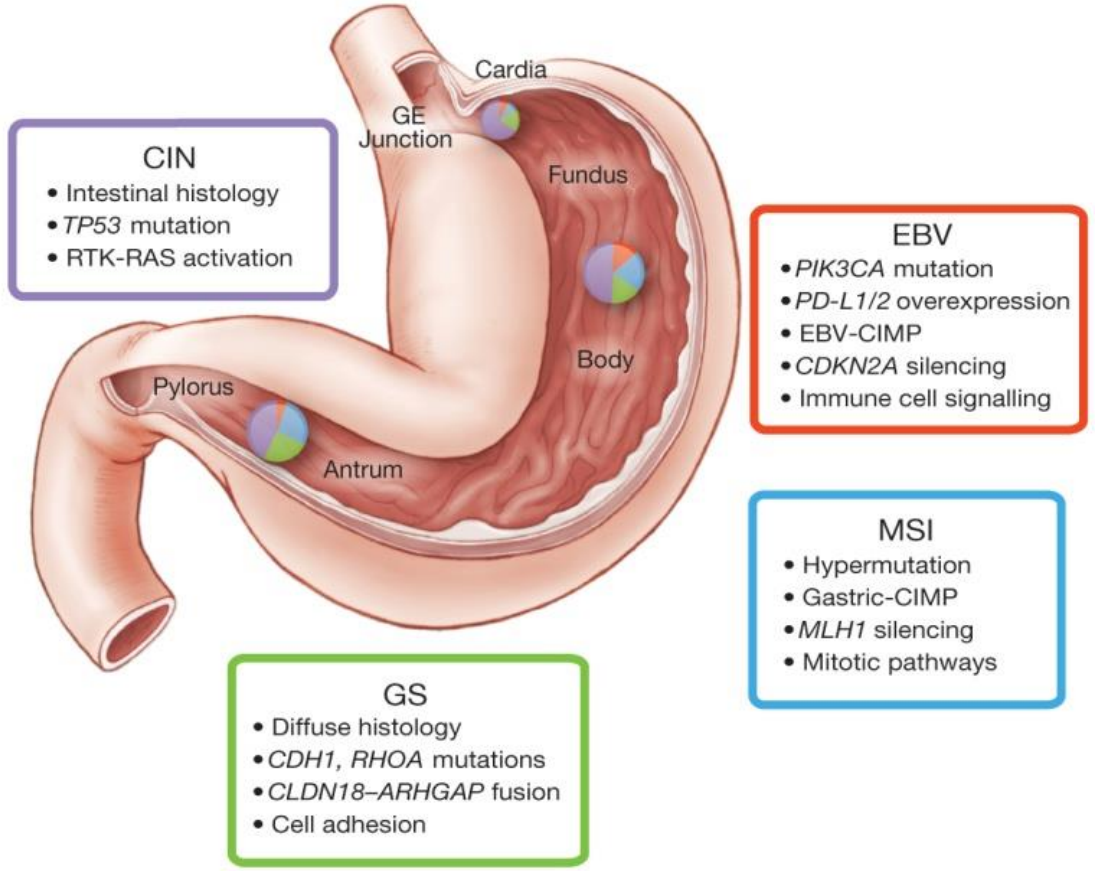
„Das Ende meines Vortrags“

Präzisionsonkologie perioperativ: Jetzt und in Zukunft

Magen-/Übergangskarzinome – TCGA Klassifikation

Vier Subtypen:

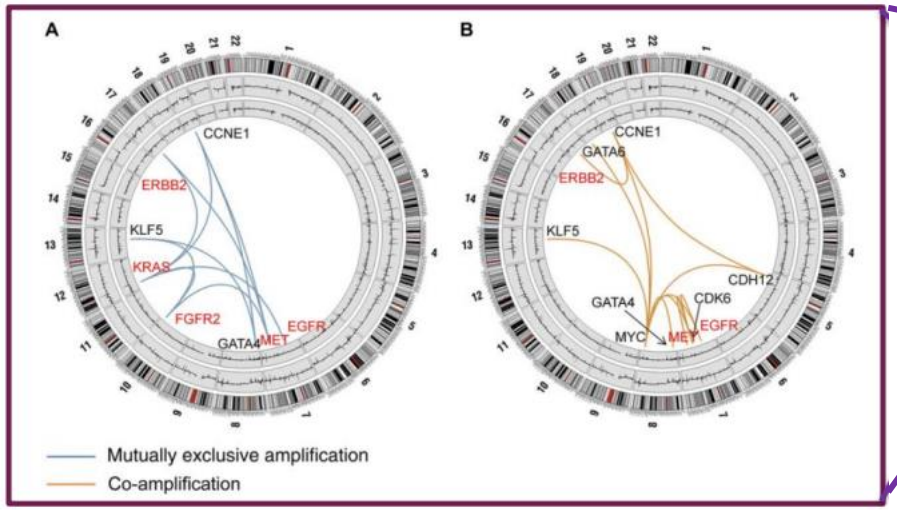
- **CIN:** Chromosomale Instabilität
- **GS:** Genomisch Stabil
- **MSI:** Mikrosatelliten-Instabil
- **EBV:** Epstein-Barr-Virus



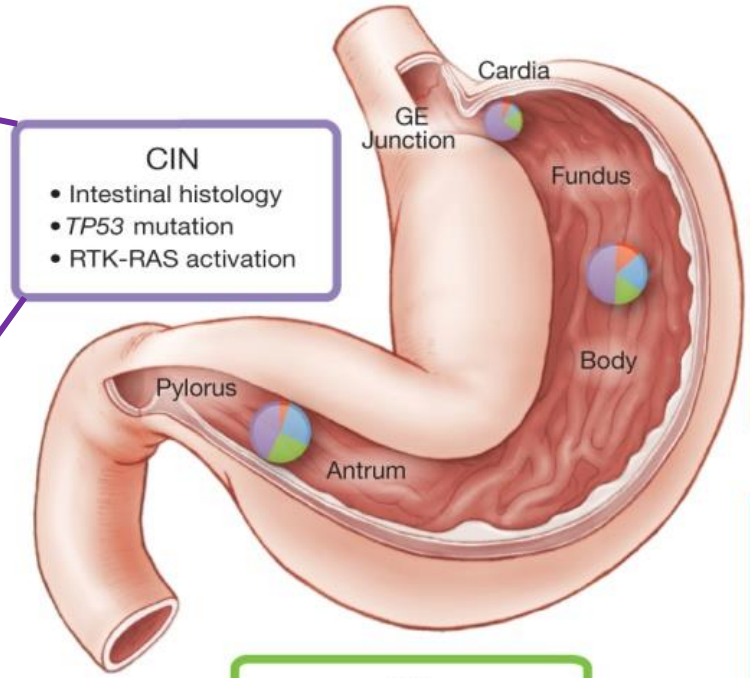
TCGA, Nature 2014;513:202-209.

Tumorbiologie Magen/GEJ-Karzinome

CIN Subtyp



Receptor Tyrosine Kinase Activation
Deng N, et al. *Gut* 2012;61:673-84



CIN
- Intestinal histology
- *TP53* mutation
- RTK-RAS activation

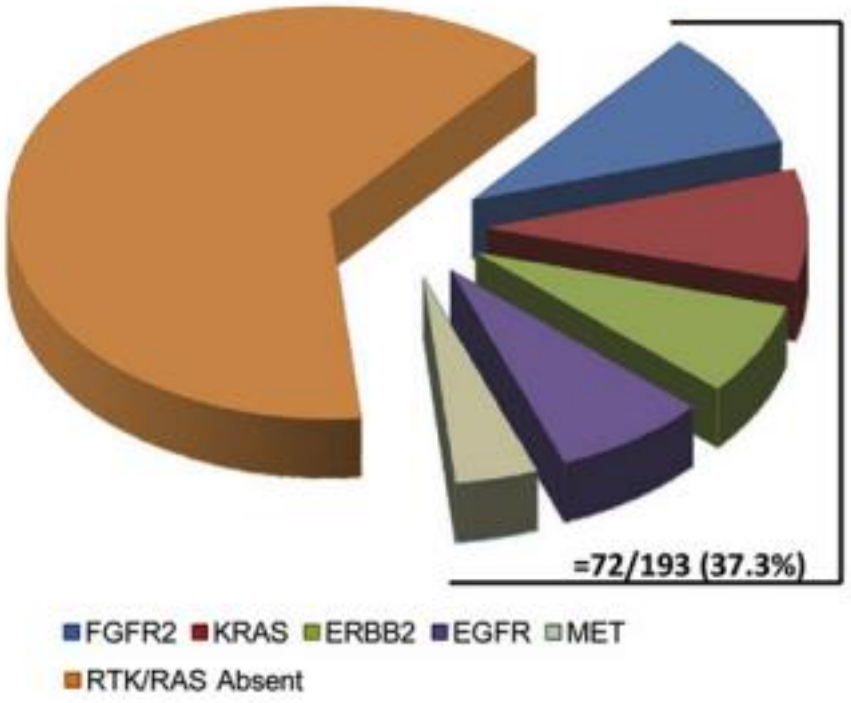
EBV
- *PIK3CA* mutation
- *PD-L1/2* overexpression
- EBV-CIMP
- *CDKN2A* silencing
- Immune cell signalling

MSI
- Hypermutation
- Gastric-CIMP
- *MLH1* silencing
- Mitotic pathways

GS
- Diffuse histology
- *CDH1, RHOA* mutations
- *CLDN18–ARHGAP* fusion
- Cell adhesion

Tumorbiologie Magen/GEJ-Karzinome

CIN Subtyp



Deng et al, Gut 2012;61:673-684.

Anti-HER2

Positive Phase-3: ToGA, Bang et al, Lancet 2010

Positive Phase-2: Destiny Gastric02, Van Cutsem, Ann Oncol 2022

Anti-EGFR

Negative Phase-3: EXPAND, REAL3

Lordick et al, Lancet Oncol 2013

Waddell et al, Lancet Oncol 2013

Anti-MET

Negative Phase-3: MetMab, RiloMet

Shah et al, JAMA Oncol 2017

Catenacci et al, Lancet Oncol 2017

Anti-FGFR

Negative Phase-2: Shine

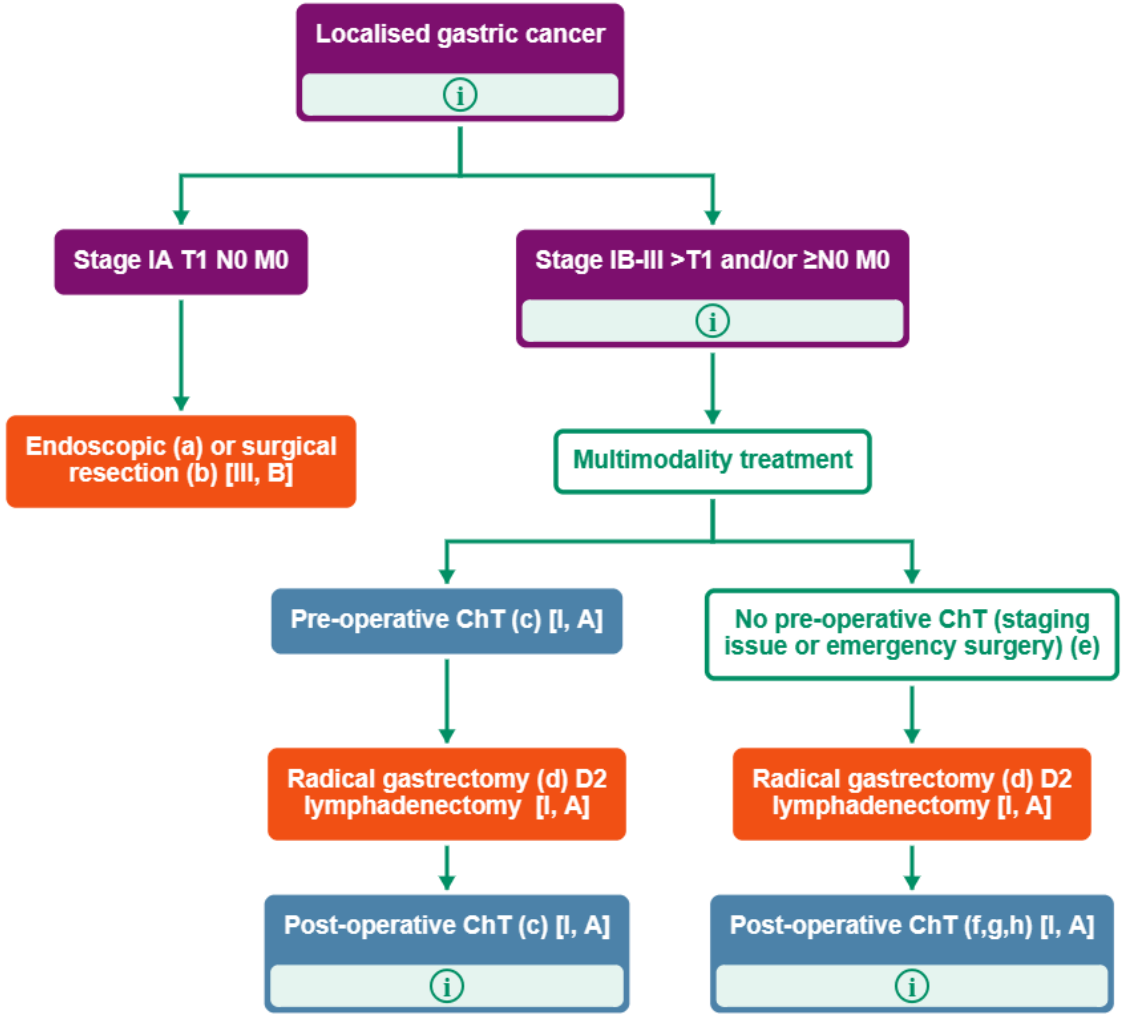
Van Cutsem et al, Ann Oncol 2017

Positive Phase-3: FIGHT

Wainberg et al, J Clin Oncol 2021

Her2-gerichtete Therapie Neoadjuvant

ESMO Gastric Cancer Living Guideline



(c) A triplet ChT regimen including a fluoropyrimidine, a platinum compound and docetaxel should be given when possible. Recommended treatment duration is 2-3 months pre- and post-operatively.

Präzisionsonkologie perioperativ: Jetzt und in Zukunft

Her2-gerichtete Therapie: HerFLOT-Studie

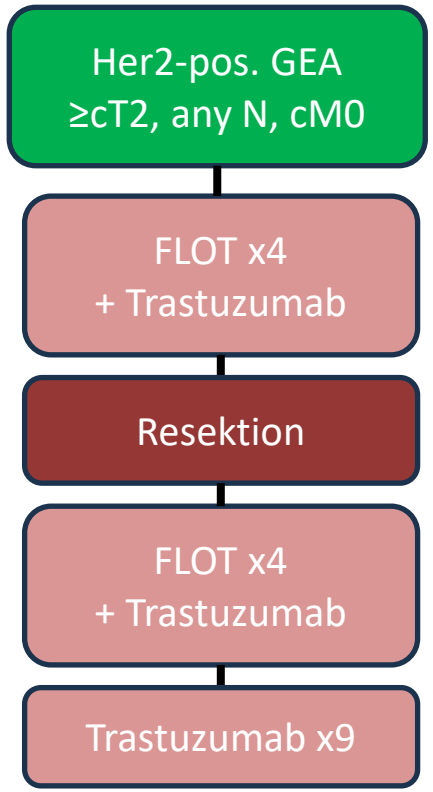


TABLE 3 Surgery and surgical morbidity of patients included in the intention-to-treat population (n = 56)

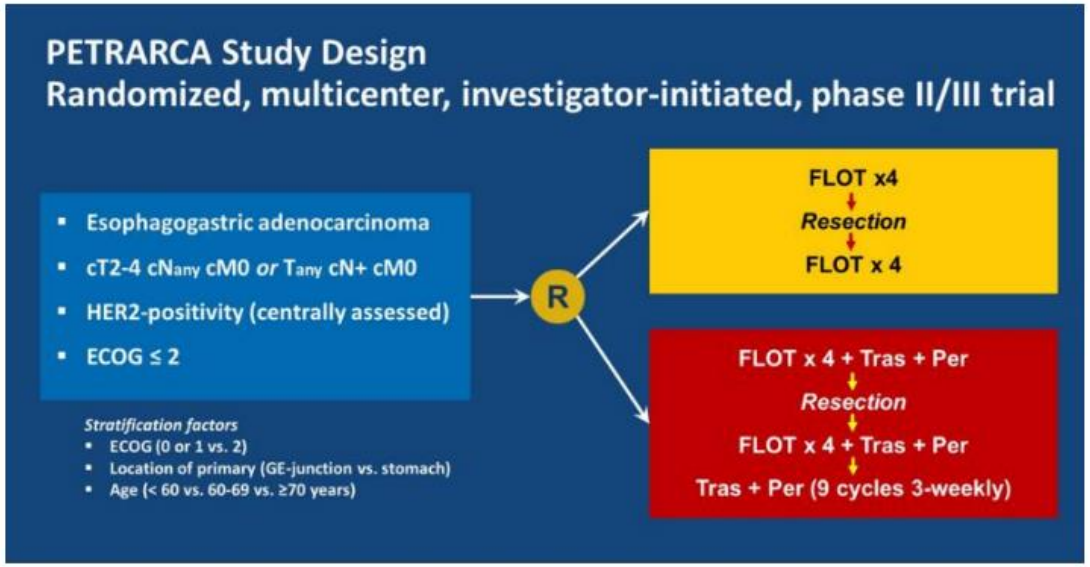
Event	N	%
Operated	56	100
Resected	56	100
R0	52	92.9
R1	2	3.6
Unknown	2	3.6

ITT population	N	%
Regression grading according to Becker (centrally assessed, primary endpoint)	12	21.4
Complete response (No residual tumor)	14	25.0
Subtotal response (<10% residual tumor)	10	17.9
Partial response (10%-50% residual tumor)	15	26.8
Minor response (>50% residual tumor)	4	7.1
No response	1	1.8
Not determined		
ypT status (locally determined)		
0	13	23.2
1	6	10.7
2	8	14.3
3	24	42.9
4	5	8.9
ypN status (locally determined)		
Negative	33	58.9
Positive	23	41.1

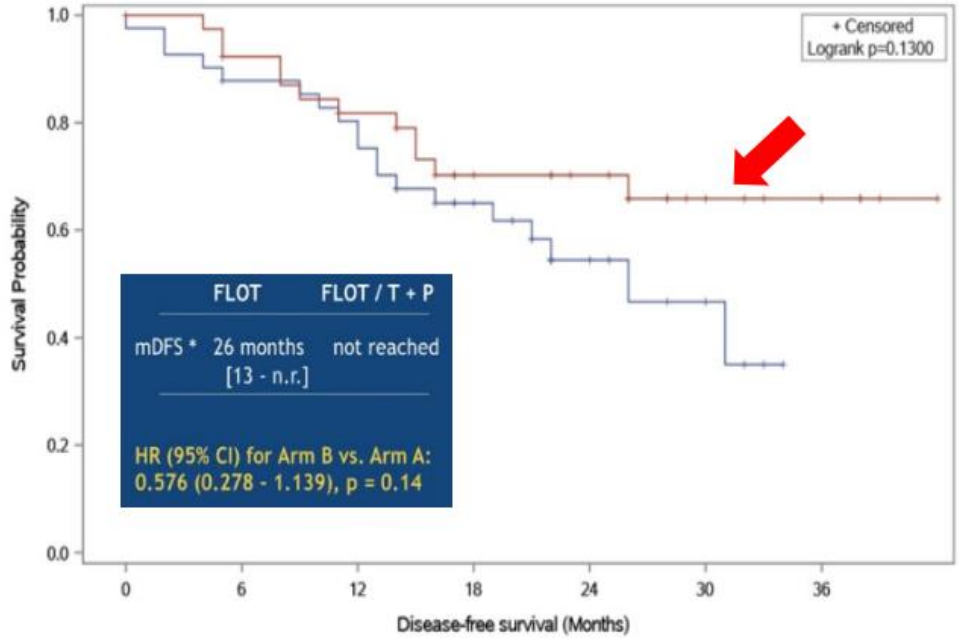
Hofheinz et al, Int J Cancer 2021;49:1322-1331.

Präzisionsonkologie perioperativ: Jetzt und in Zukunft

Her2-gerichtete Therapie: PETRARCA-Studie



Study	FLOT	FLOT + P + T	p
pCR	12%	35%	0.02

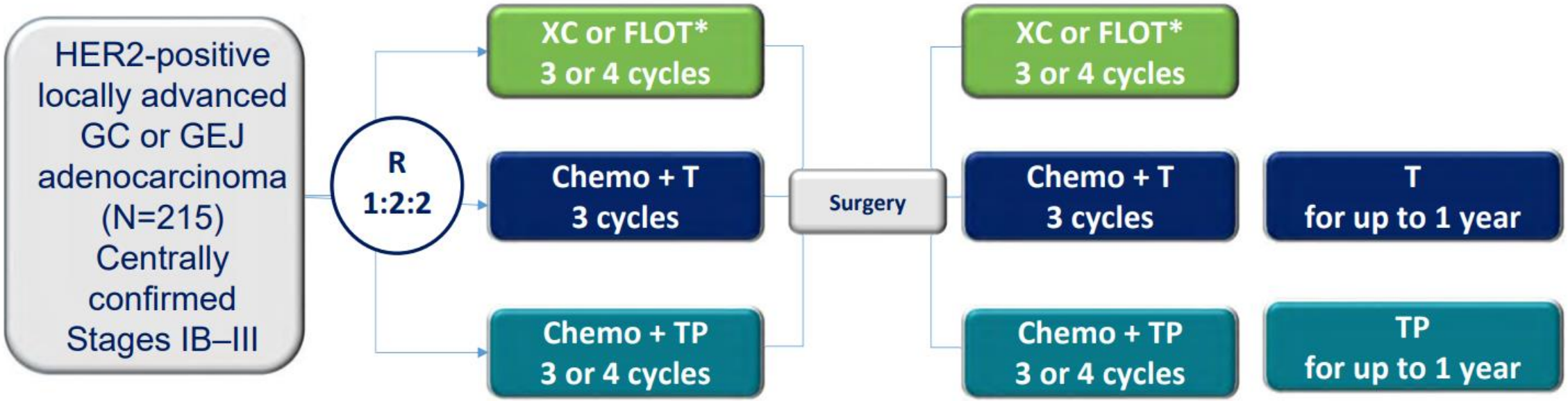


- Frühe Beendigung als Phase II
- ↑ pCR
- Trend zur verlängertem DFS
- Laufende Phase III EORTC-INNOVATION

Hofheinz et al, J Clin Oncol 2020;38; abstract 4502.

Präzisionsonkologie perioperativ: Jetzt und in Zukunft

Her2-gerichtete Therapie: EORTC 1203 INNOVATION-Studie



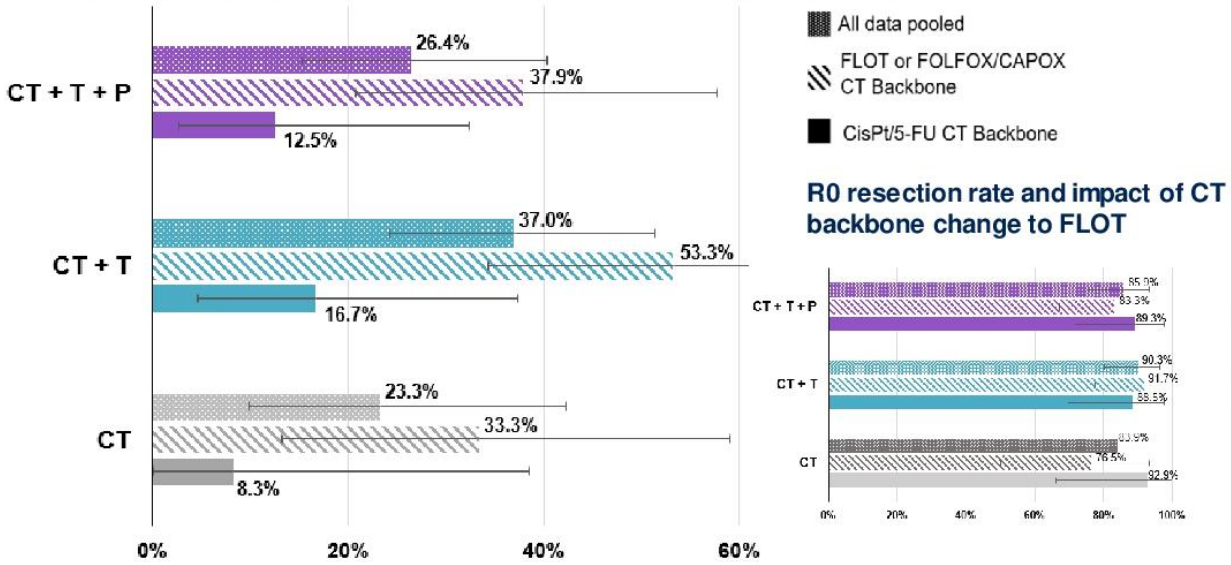
T = trastuzumab; P = pertuzumab

Wagner et al, ASCO 2023, abstract 4057.

Präzisionsonkologie perioperativ: Jetzt und in Zukunft

Results:

Primary endpoint analysis mpRR (%) and impact of CT backbone change to FLOT



R0 resection rate and impact of CT backbone change to FLOT

The increase of 3.1% (80% CI [-9.5%, 15.7%], one sided p=0.378) in CT+T+P arm *vs* CT arm was not statistically significant.
The increase in CT+T arm *vs* CT arm was of 13.7% (80% CI [0.7%, 26.7%], one sided p=0.099).

Adverse events

AEs with frequency > 15% in at least one arm, during neoadjuvant treatment, N (%)	Safety population					
	CT (n=34)		CT + T (n=66)		CT+ T + P (n=69)	
	Grade 3-5	All grades	Grade 3-5	All grades	Grade 3-5	All grades
Patients' worst grade	12 (35.3)	32 (94.1)	32 (48.5)	64 (97.0)	48 (69.6)	66 (95.7)
Anemia		1 (2.9)		3 (4.5)	2 (2.9)	11 (15.9)
Diarrhea	1 (2.9)	11 (32.4)	2 (3)	33 (50)	15 (21.7)	47 (68.1)
Mucositis oral	1 (2.9)	4 (11.8)	1 (1.5)	12 (18.2)	7 (10.1)	18 (26.1)
Nausea		14 (41.2)	2 (3)	28 (42.4)	8 (11.6)	33 (47.8)
Vomiting		1 (2.9)	1 (1.5)	6 (9.1)	2 (2.9)	18 (26.1)
Fatigue		10 (29.4)	3 (4.5)	19 (28.8)	3 (4.3)	23 (33.3)
Neutrophil count decreased	9 (26.5)	14 (41.2)	16 (24.2)	30 (45.5)	14 (20.3)	26 (37.7)
Weight loss				4 (6.1)		13 (18.8)
White blood cell decreased		1 (2.9)		6 (9.1)	3 (4.3)	13 (18.8)
Anorexia		9 (26.5)	1 (1.5)	13 (19.7)	3 (4.3)	15 (21.7)
Dysgeusia		6 (17.6)		7 (10.6)		8 (11.6)
Paresthesia		6 (17.6)		12 (18.2)		8 (11.6)
Peripheral sensory neuropathy		5 (14.7)		10 (15.2)		9 (13)
Epistaxis		1 (2.9)				11 (15.9)

Exposure to neoadjuvant treatment

Neoadjuvant treatment after FLOT CT backbone amendment	Safety population (FLOT CT Backbone only)		
	CT (N=16)	CT + T (N=30)	CT + T + P (N=31)
Number of cycles of FLOT, N (%)			
4	15 (93.8)	28 (93.3)	25 (80.6)
FLOT Relative Dose intensity* (%) – Median			
Oxaliplatin	99.0	93.9	87.9
Docetaxel	98.1	94.0	85.5
Folinic acid	99.1	94.6	93.2
5-FU	99.5	94.1	82.0
Trastuzumab		98.7	100.0
Pertuzumab			100.0

**calculated based on the number of cycles actually started by the patient*

Wagner et al, ASCO 2023, abstract 4057.

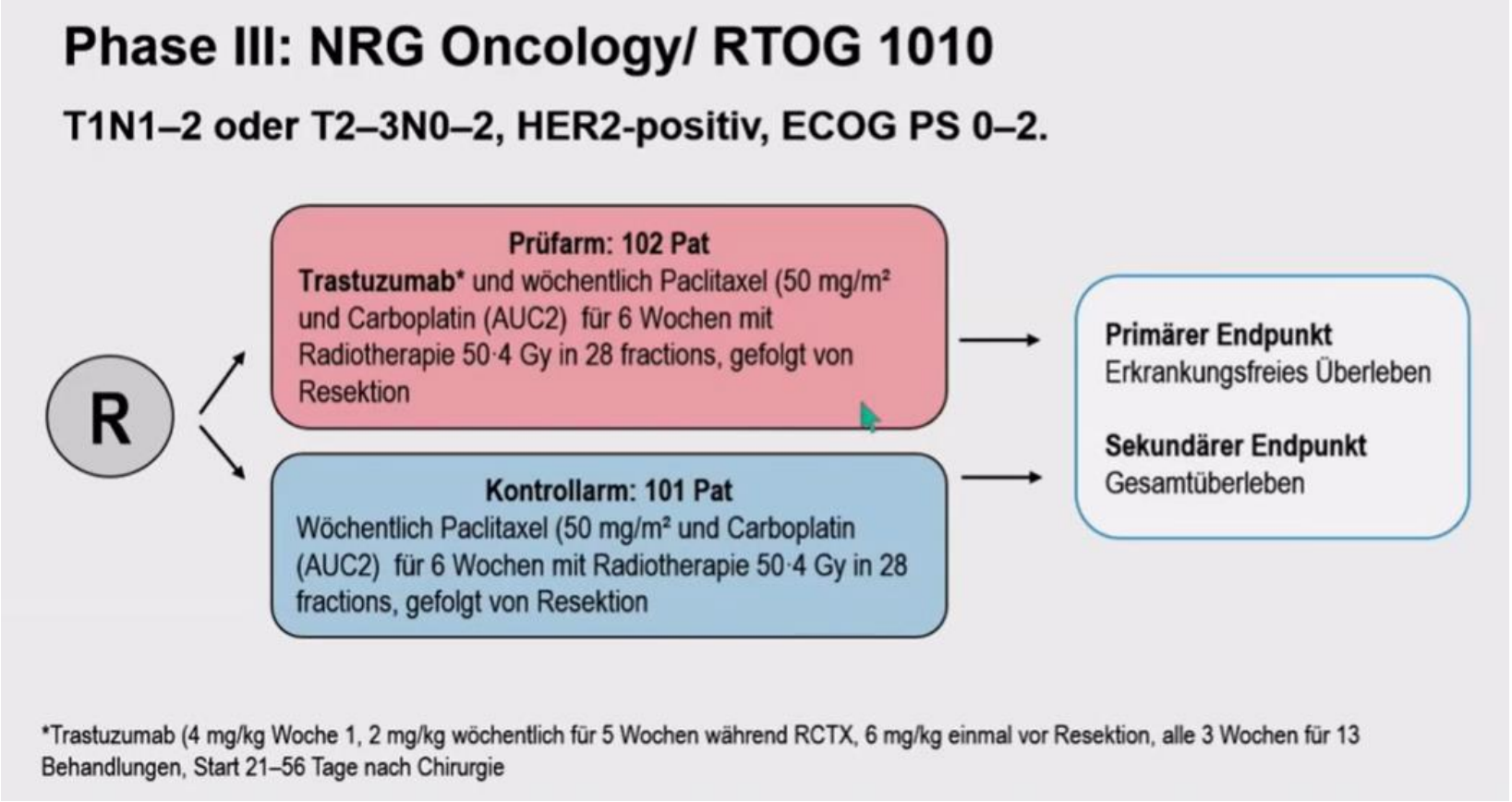
Präzisionsonkologie perioperativ: Jetzt und in Zukunft

Her2-gerichtete Therapie: Überblick

Trial	Phase	Treatment	pCR (mpRR*)	DFS (median)
HerFLOT	II	FLOT + Trastuzumab	21%	42.5 Monate
PETRARCA	II	FLOT vs FLOT/Trast/Pert	12% vs 41%	26 Monate vs nicht erreicht
INNOVATION	II	CTx vs CTx/Trast vs CTx/Trast/Pert	23% vs 37% vs 26% *	Nicht berichtet
TRIGGER	II	S1/Cisplatin ± Trastuzumab	23% vs 50%	Nicht berichtet

Präzisionsonkologie perioperativ: Jetzt und in Zukunft

Her2-gerichtete Therapie Neoadjuvant zur Radiatio



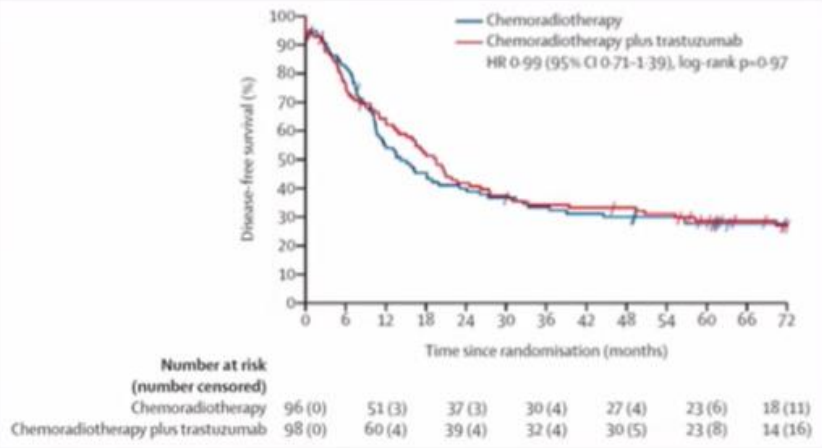
Safran et al, Lancet Oncol 2022;23:259-269.

Präzisionsonkologie perioperativ: Jetzt und in Zukunft

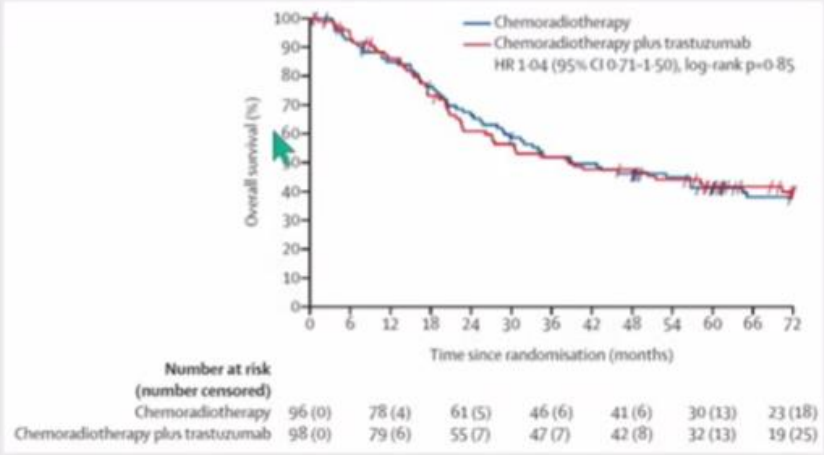
Her2-gerichtete Therapie Neoadjuvant zur Radiatio

Phase III: NRG Oncology/ RTOG 1010

Erkrankungs-freies Überleben



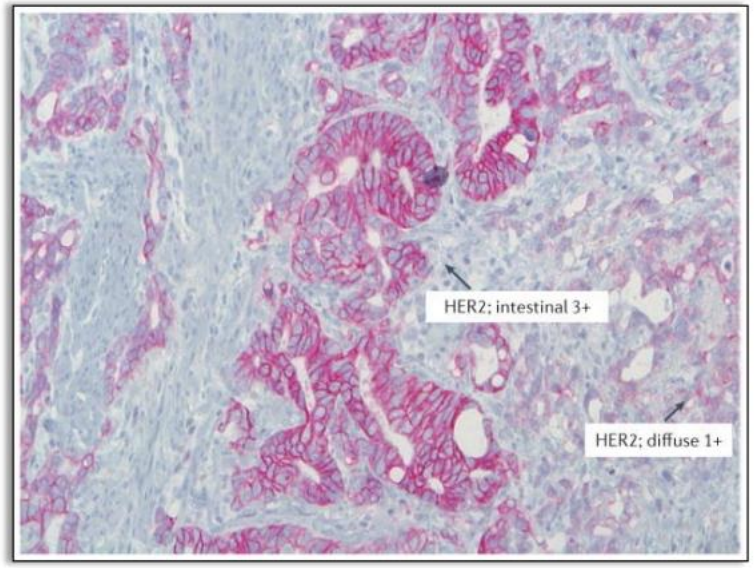
Gesamtüberleben



Safran et al, Lancet Oncol 2022;23:259-269.

Präzisionsonkologie perioperativ: Jetzt und in Zukunft

Hürden: Intratumorale Her2-Heterogenität



TOGA HER2 heterogeneity by IHC score	
Heterogeneity = ≤ 30% staining	
IHC3+	30%

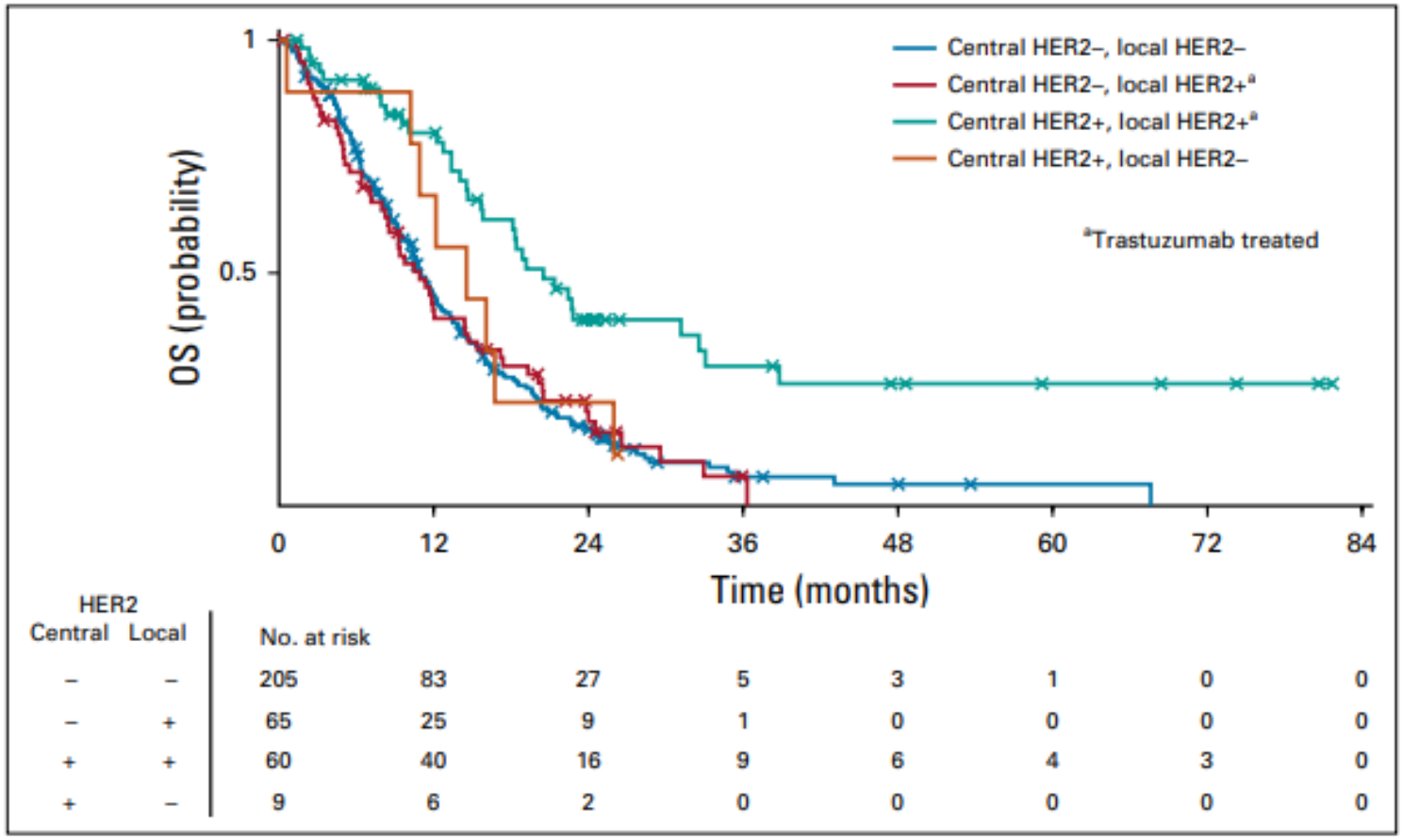
TOGA HER2 % of positive cells in IHC3 + patients				
% cells	<10%	10-30%	31-79%	≥80%
% patients	3%	27%	31%	39%

Many patients have only a small proportion of their tumour addicted to HER2 signalling

Lordick et al, Nat Rev Clin Oncol 2016;13:348-360. Van Cutsem et al, Gastric Cancer 2015;18:476-484.

Präzisionsonkologie perioperativ: Jetzt und in Zukunft

VARIANZ-Studie: Intratumorale Her2-Heterogenität und Prognose



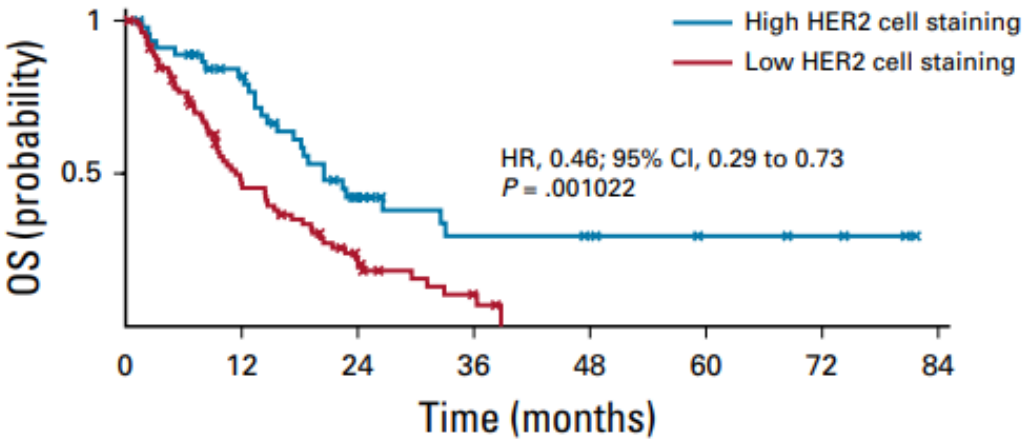
HER2 Central	HER2 Local	No. at risk							
–	–	205	83	27	5	3	1	0	0
–	+	65	25	9	1	0	0	0	0
+	+	60	40	16	9	6	4	3	0
+	–	9	6	2	0	0	0	0	0

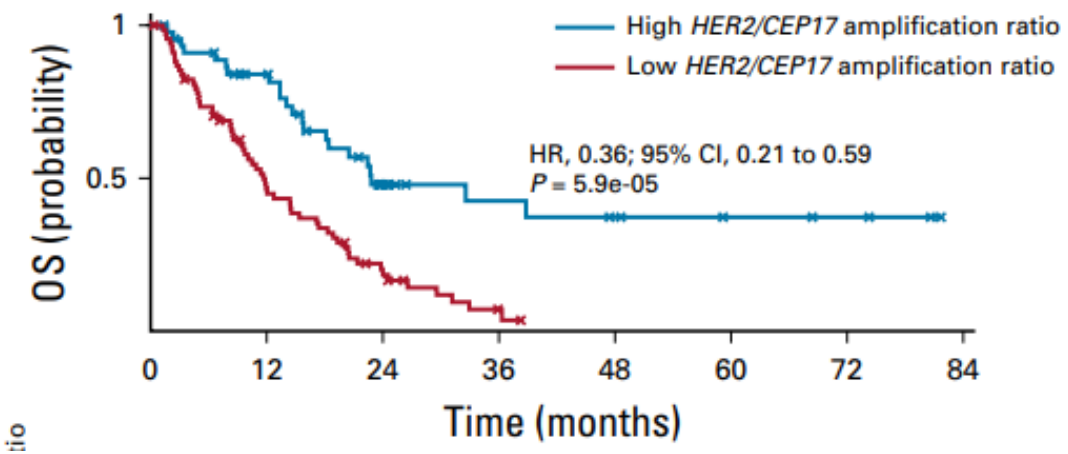
Haffner et al, J Clin Oncol 2021;39:1468-1478.

Präzisionsonkologie perioperativ: Jetzt und in Zukunft

Neue Her2-Cutoffs?

VARIANZ-Studie:
vorgeschlagene optimisierte cut-offs für 1L Trastuzumab
ICH: 40% positive Zellen
CEP17:Her2 Ratio ≥ 3.0

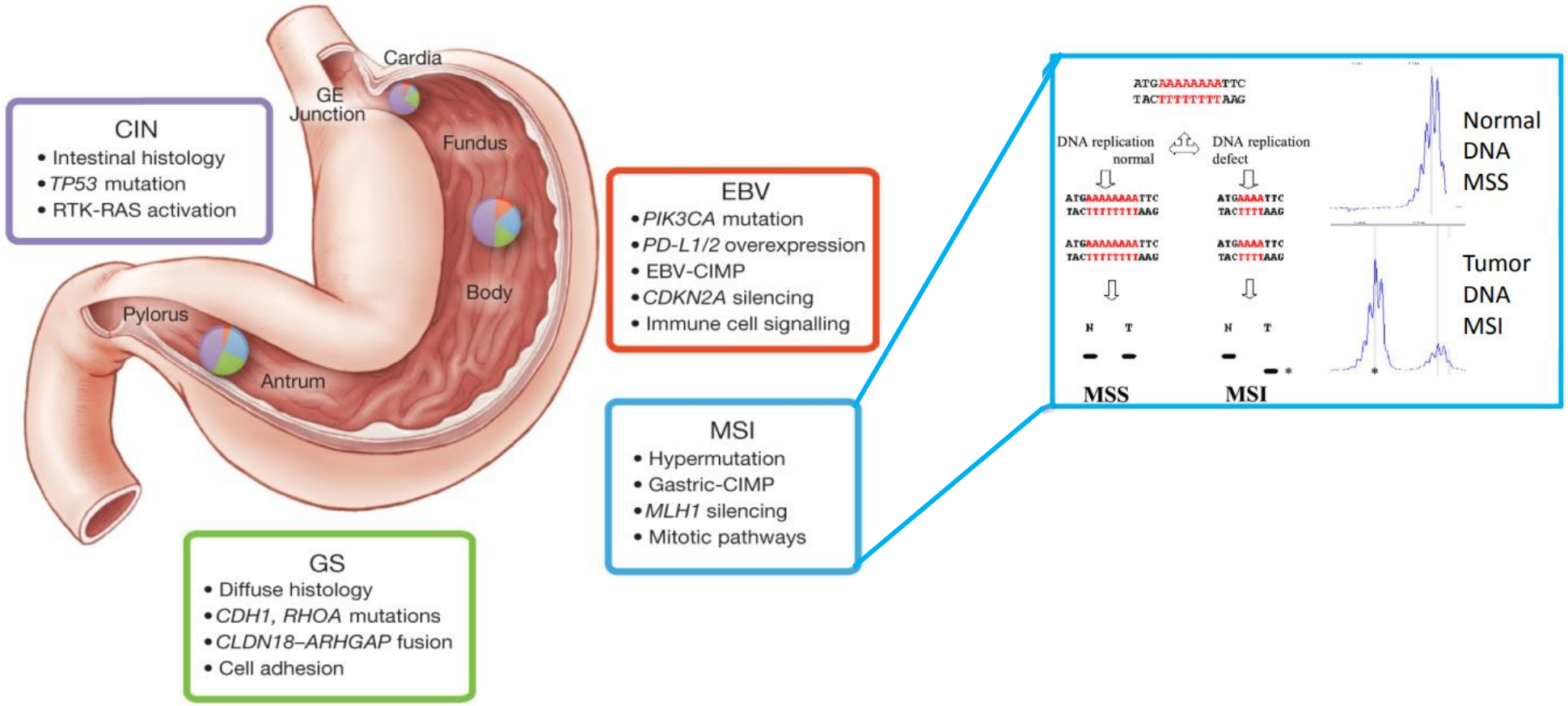




Haffner et al, J Clin Oncol 2021;39:1468-1478.

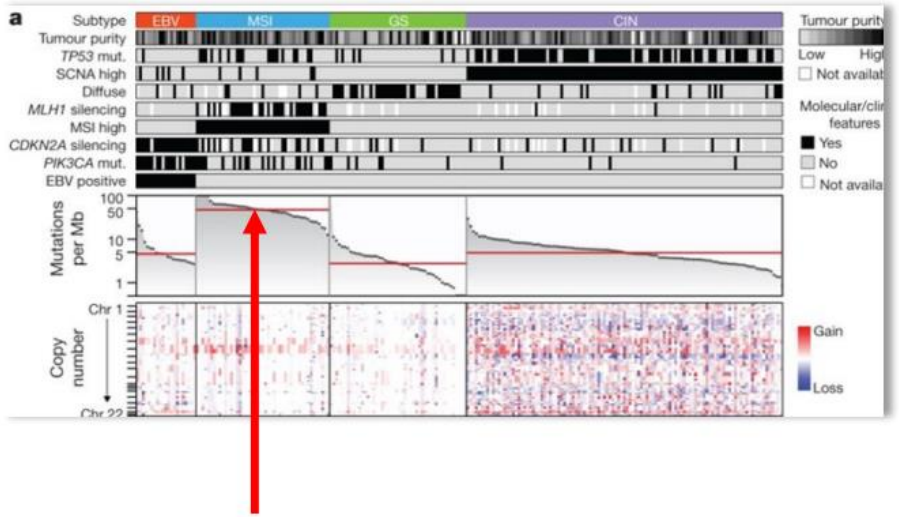
Tumorbiologie Magen/GEJ-Karzinome

MSI-H Subtyp

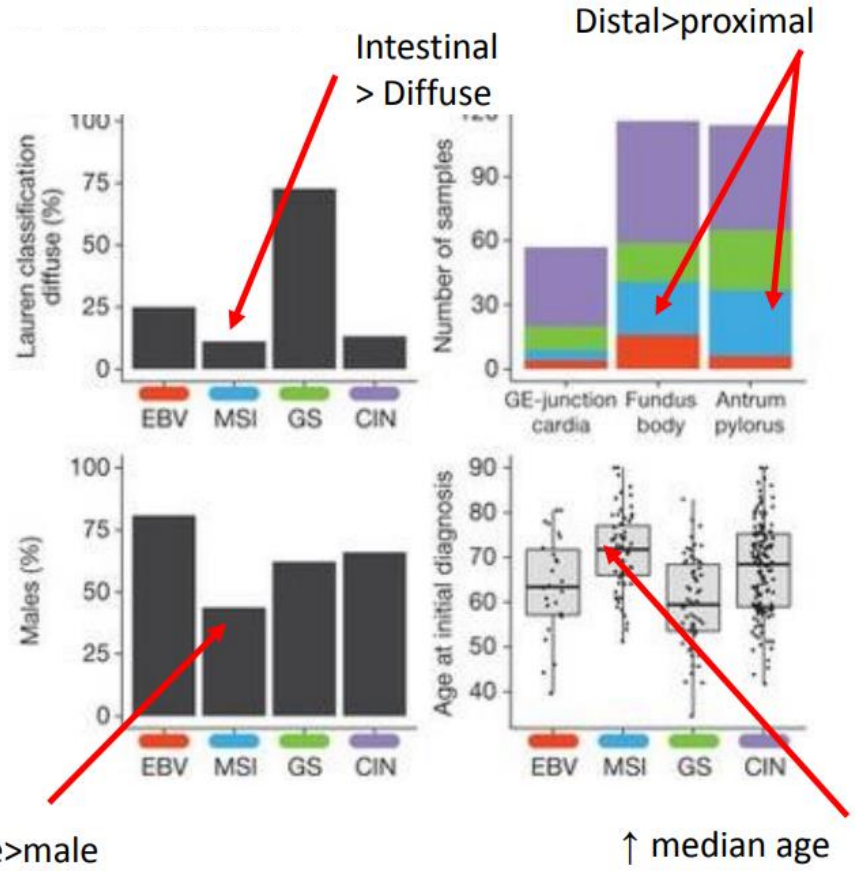


Tumorbiologie Magen/GEJ-Karzinome

MMRd/MSI-h Subtyp



High mutational burden



Female>male

↑ median age

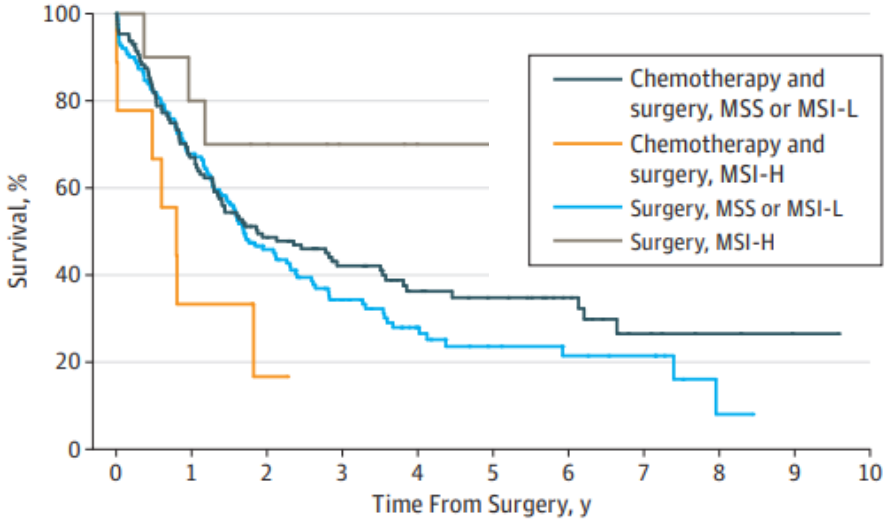
8%-10% operables Stadium
3%-5% Stadium IV

Bass et al, Nature 2014;513:202-209.

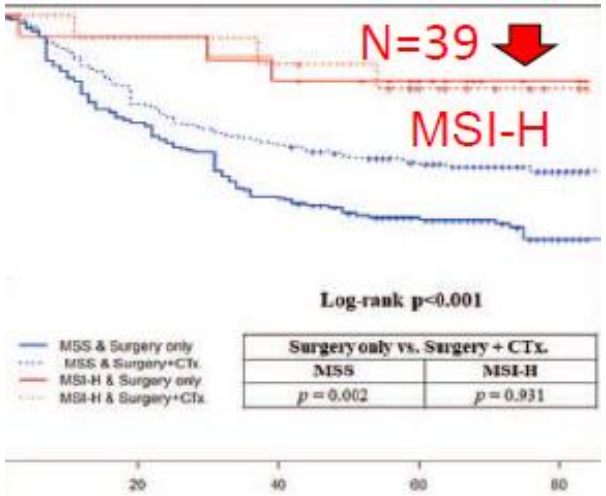
Präzisionsonkologie perioperativ: Jetzt und in Zukunft

Perioperative Chemotherapie bei MSI-H/dMMR

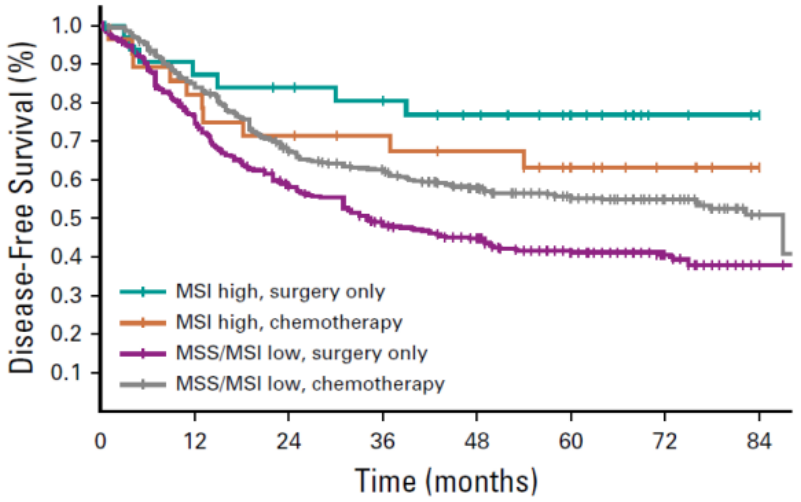
MAGIC



CLASSIC



Metaanalyse

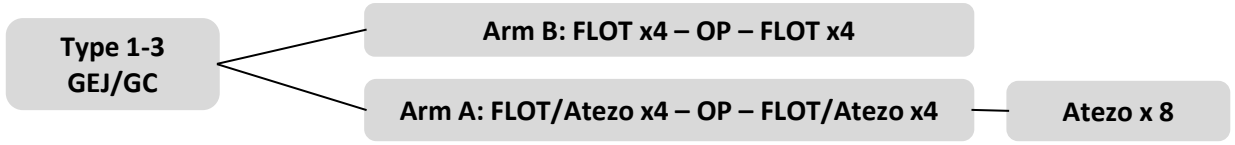


Smyth et al, JAMA Oncol 2017;24:1449-1458; Choi et al, Ann Surg 2019;270:309-316; Pietrantonio et al, J Clin Oncol 2019;37:3392-3400..

Intrinsische Resistenz gegenüber Platinen und 5FU

Präzisionsonkologie perioperativ: Jetzt und in Zukunft

AIO-DANTE: FLOT bei MSI-H/dMMR Magen-Ca



Pathological Regression **FLOT + Atezolizumab (arm A) vs. FLOT (arm B)**	**Becker Classification**			
	TRG1a[1]		**TRG1a/b[2]**	
	A	**B**	**A**	**B**
All patients (N= 295; 146|149)	35 (24%)	23 (15%)	71 (49%)	58 (39%)
PD-L1 CPS ≥1 (N=170; 82|88)	20 (24%)	13 (15%)	42 (51%)	40 (46%)
PD-L1 CPS ≥5 (N=81; 40|41)	11 (28%)	8 (20%)	22 (55%)	18 (44%)
PD-L1 CPS ≥10 (N=53; 27|26)	9 (33%)	3 (12%)	18 (67%)	10 (39%)
MSI high (N=23; 8|15)	5 (63%)	4 (27%)	6 (75%)	7 (47%)

Al Batran et al, ASCO 2022, abstract 4003.

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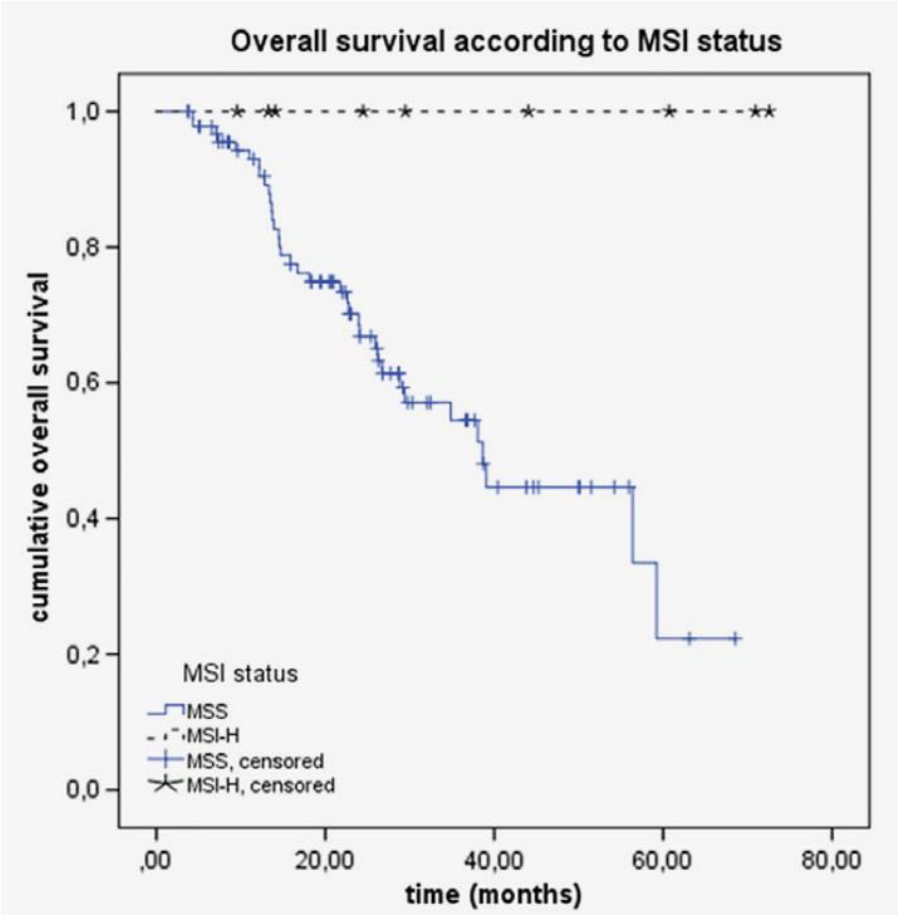
Heidelberg Kohorte MSI-H/dMMR GEJ/Magen-Ca

Table 3. Histological regression after neoadjuvant treatment (100 cases evaluable)

Regression according to Becker classification	MSS (91 cases)	MSI-H (9 cases)
TRG 1a (complete response)	0 (0.0%)	1 (11.1%)
TRG 1b (<10% vital tumor)	19 (20.9%)	0 (0.0%)
TRG 2 (10–50% vital tumor)	26 (28.6%)	0 (0.0%)
TRG 3 (>50% vital tumor)	46 (50.5%)	8 (88.9%)

- 55% erhielten neoadjuvant FLOT
- obwohl häufiger TRG3 besseres OS in MSI vs MSS



Haag et al, Int J Cancer 2019;144:1697-1703.

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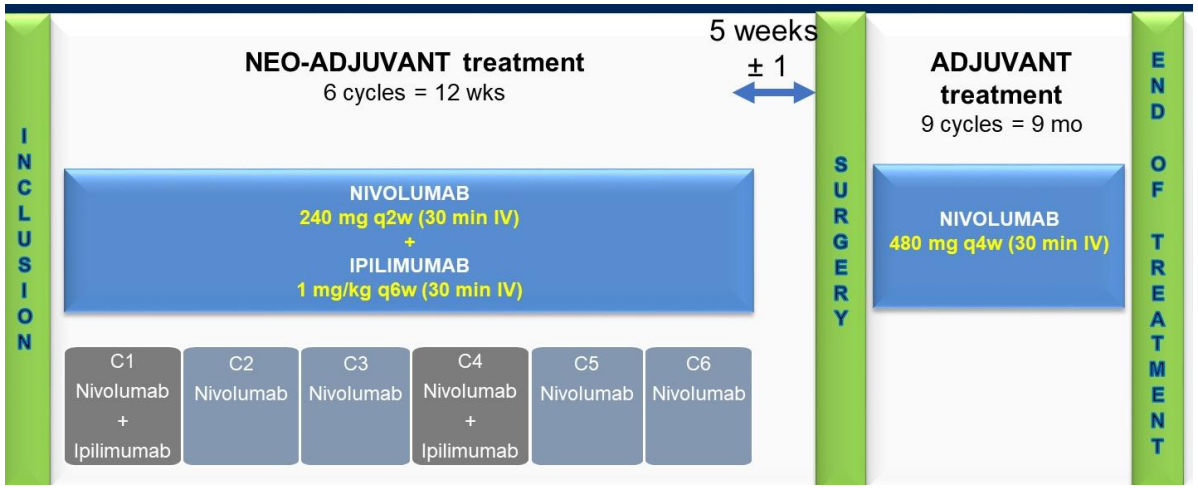
MSI-H/dMMR – Immuntherapie neoadjuvant

NEONIPIGA-Studie



TRG Mandard (N=29)	N	%
TRG 1: complete regression/fibrosis with no tumor cells	17	58.6
TRG 2: fibrosis with scattered tumor cells	4	13.8
TRG 3: fibrosis and tumor cells with a dominance of fibrosis	2	6.9
TRG 4: fibrosis & tumor cells with dominance of tumor cells	4	13.8
TRG 5: tumor without evidence of regression	2	6.9
TRG Becker (N=29)		
TRG 1a: complete tumor regression without residual tumor	17	58.6
TRG 1b: < 10% residual tumor per tumor bed	4	13.8
TGR 2: 10% to 50% residual tumor	2	6.9
TRG 3: > 50% residual tumor cells	6	21.7

Andre et al, ASCO GI 2022, abstract 244.

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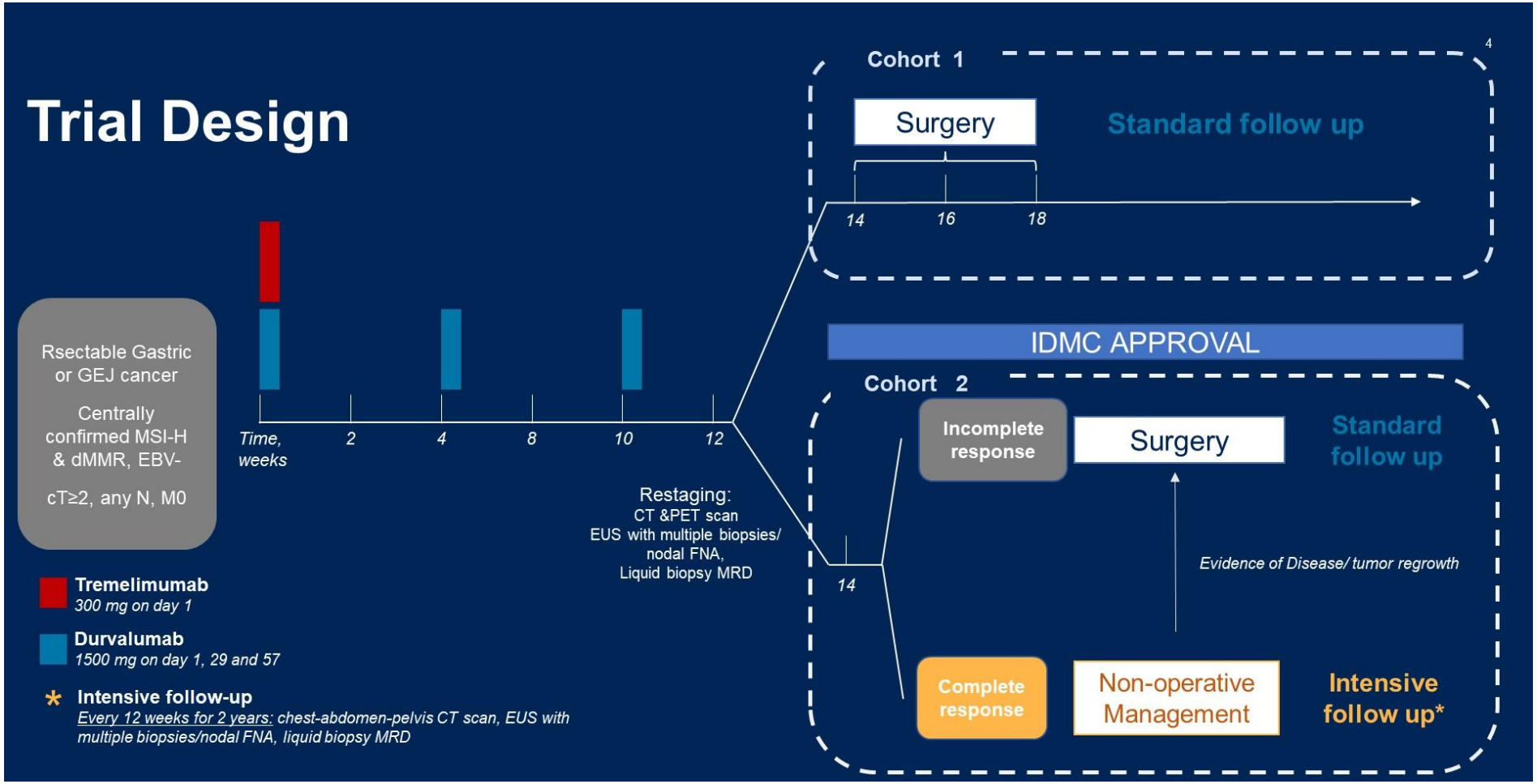
INFINITY: Neoadjuvante Immuntherapie



Ziel:
pCR und
ctDNA-Negativität

Pietrantonio ASCO Gi 2023; abstract 358.

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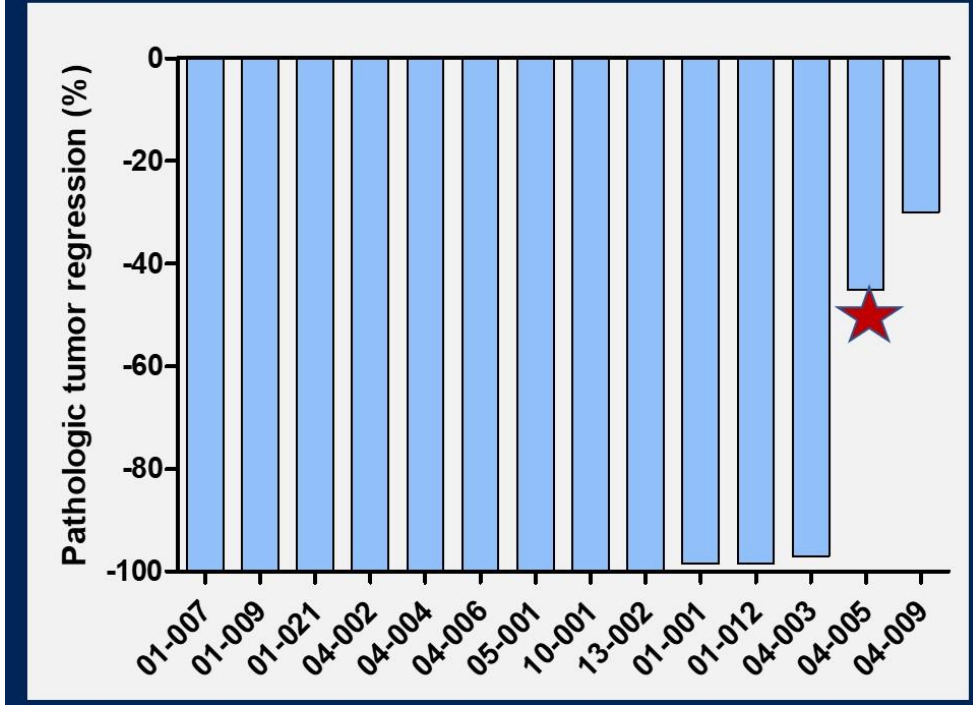
Primary endpoint



TRG Becker	N = 15	%
1a	9	60%
1b	3	20%
3	2	13%

1 patient did not undergo surgery for PD

Among evaluable patients, rate of pCR was 60% and rate of major to complete pathological response (<10% viable cells) was 80%.

★ Heterogeneous pMMR/dMMR status at surgery

Pietrantonio ASCO Gi 2023; abstract 358.

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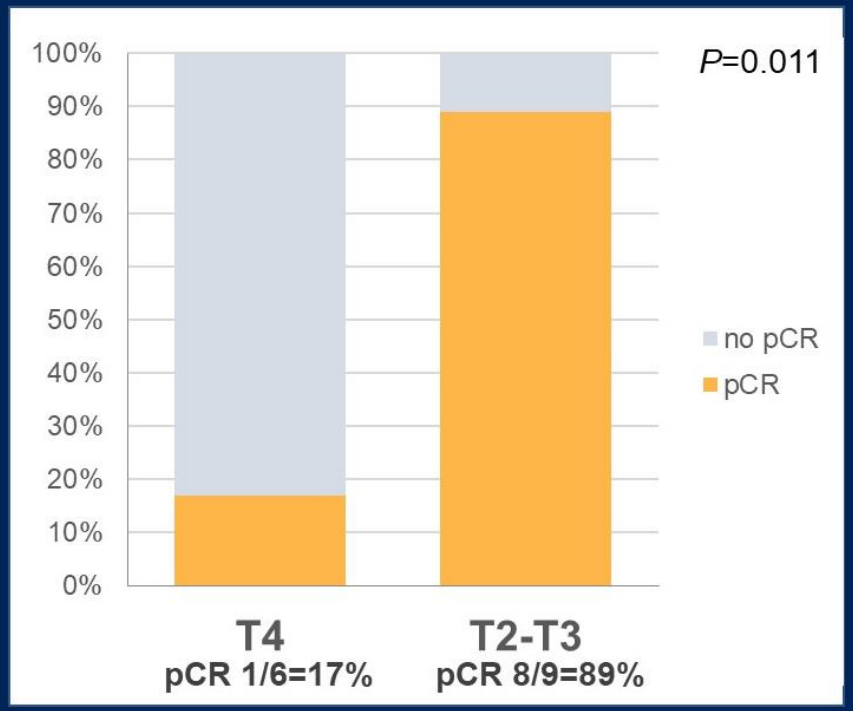
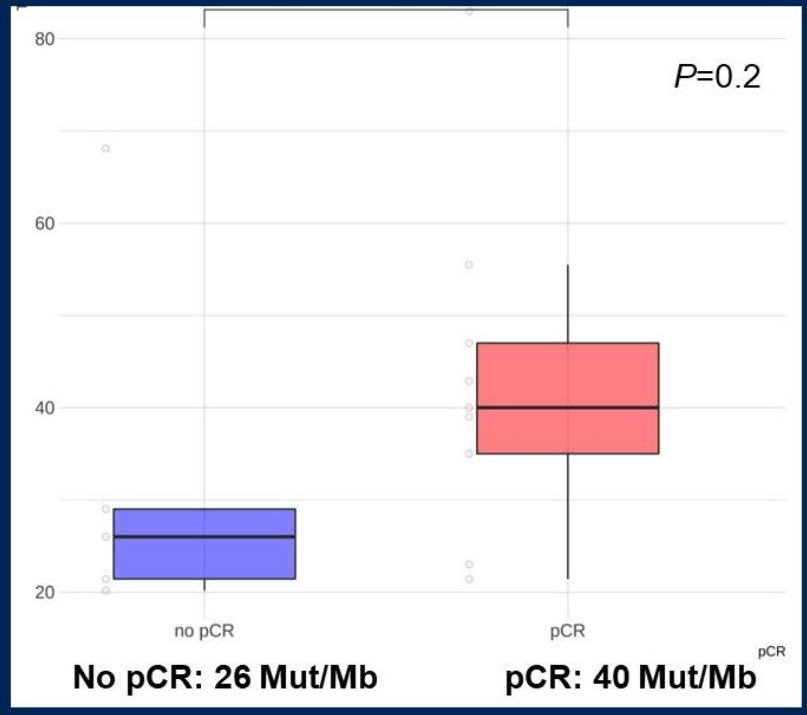
Prädiktive Faktoren

Baseline clinical staging (EUS, CT +/- laparoscopy)



Significant correlation with pCR was found for baseline **cT stage**, but not for **cN stage**.

Baseline Tumor Mutational Burden (Foundation One)



Numerical correlation with pCR was found for baseline **TMB**, but not for **PD-L1 CPS.**

Pietrantonio ASCO Gi 2023; abstract 358.

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Laufende Studien Immuntherapie resektables GEJ/Magen-Ca

Studie	Phase	Therapiearme	1. Endpunkt	
MATTERHORN	III	FLOT ± Durvalumab	EFS	**↑pCR**
KEYNOTE 585	III	Chemo ± Pembrolizumab	EFS, pCR, OS	**↑pCR, EFS n.s.**
NEONIPIGA	II	Nivolumab/Ipilimumab	pCR	
INFINITY	II	Tremelimumab/Durvalumab	pCR, ctDNA	
VESTIGE	II	Adj. Chemo vs adj. Nivo/Ipi	DFS	
ATTRACTION 5	III	Adj. Chemo vs Adj.Chemo+Nivo	RFS	
IMAGINE	II	FLOT/Nivo vs Nivo/Relatlimab	pCR	
IMHOTEP	II	Pembrolizumab	pCR	
GASPAR	II	FLOT/Spartalizumab	pCR	

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ATTRACTION 5: negatives Ergebnis

Key eligibility criteria
- pStage III GC/GEJC
- D2 or more extended gastrectomy
- ECOG PS 0-1
- Tumour tissue for PD L1 analysis

Investigator's choice of adjuvant chemotherapy
S-1[b] or CapeOX[c]

R 1:1

N=755

Nivolumab 360 mg IV Q3W + Chemotherapy (N=377)

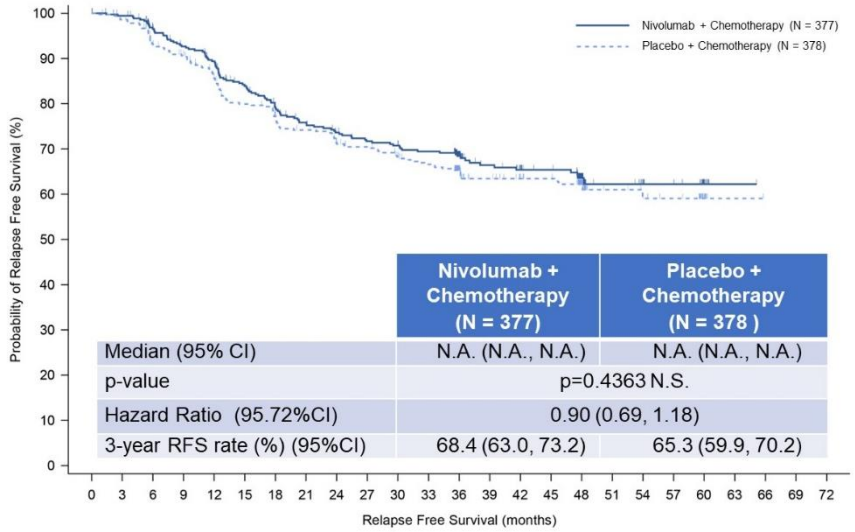
Placebo IV Q3W + Chemotherapy (N=378)

Primary endpoint:
- RFS per BICR

Secondary endpoints:
- RFS per investigator
- OS
- Safety

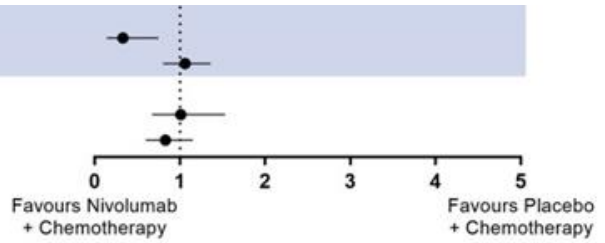
Stratification factors:
- **Stage (IIIA/IIIB/IIIC)**
- **Country (Japan/Korea/Other)**

Treatment duration:
- **Up to 1 year (Nivolumab/Placebo, S-1)**
- **Up to 6 months (CapeOX)**



	Nivolumab + Chemotherapy (N = 377)	Placebo + Chemotherapy (N = 378)
Median (95% CI)	N.A. (N.A., N.A.)	N.A. (N.A., N.A.)
p-value	p=0.4363 N.S.	
Hazard Ratio (95.72%CI)	0.90 (0.69, 1.18)	
3-year RFS rate (%) (95%CI)	68.4 (63.0, 73.2)	65.3 (59.9, 70.2)

Tumor cell PD-L1 expression			
≥1%	9/52	15/34	0.33 (0.14-0.75)
<1%	103/309	106/333	1.06 (0.81-1.40)
Chemotherapy regimen			
S-1	46/132	45/135	1.01 (0.67-1.53)
CapeOX	67/245	79/243	0.83 (0.60-1.15)

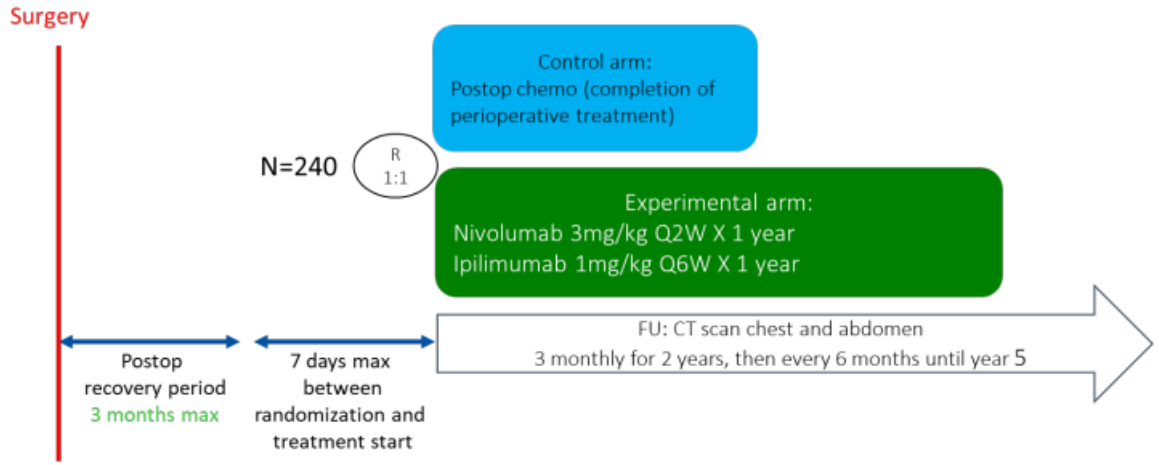


Terashima et al, ASCO 2023, abstract 4000.

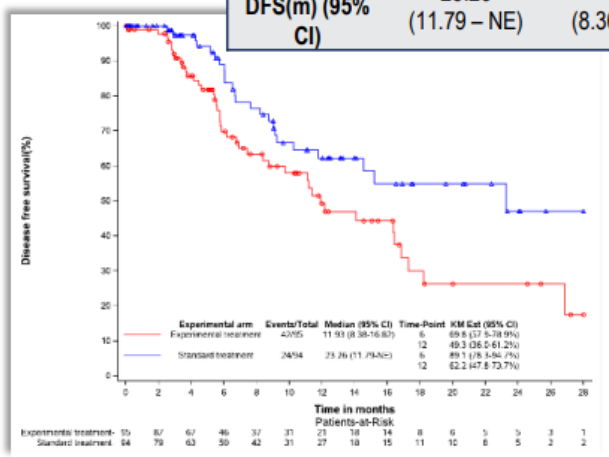
Präzisionsonkologie perioperativ: Jetzt und in Zukunft

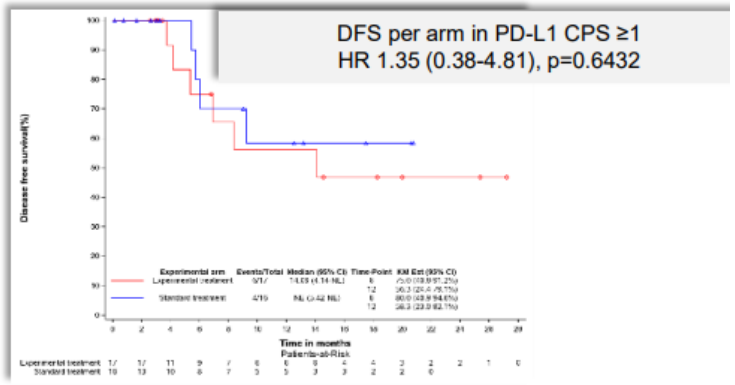
VESTIGE: negatives Ergebnis

- Gastric or EGJ adenocarcinoma stage Ib-IV
- Completed pre-operative chemotherapy with a fluoropyrimidine/platin-containing regimen followed by surgery within 12 weeks prior to randomization
- Recovered from surgery
- ypN1-3 status according to current (8th) version of TNM classification system AND/OR
- R0 or R1 resection according to current (8th) version of TNM



	CT am	Nivo/Ipi arm
Median DFS(m) (95% CI)	23.26 (11.79 – NE)	11.93 (8.36- 16.82)





Smyth et et al, WCGI 2023; abstract O6.

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Potentielle zusätzliche Targets

Perioperativ untersucht

Anti-EGFR

Negative Phase-2:

Mariette et al, J Clin Oncol 2015 (Cis/5FU/Cetuximab)

Lockhart et al, Ann Oncol 2019 (Doce/Cis/Panitumumab/RT)

Cao et al, Medicine 2021 (Nimotuzumab)

Anti-VEGF/R

Negative Phase-2/3:

Cunningham et al, Lancet Oncol 2017 (ECX ± Bevacizumab)

Al-Batran et al, J Clin Oncol 2020 (FLOT ±Ramucirumab)

Zhang et al, Cancer Manag Res 2021 (FLOT ± Apatinib)

Perioperativ nicht untersucht

Anti-FGFR

Negative Phase-2 mGC: SHINE

Van Cutsem et al, Ann Oncol 2017

Positive Phase-3 mGC: FIGHT

Wainberg et al, J Clin Oncol 2021

Anti-Claudin18.2

Positive Phase-3 mGC: SPOTLIGHT, GLOW

Shitara et al, Lancet 2023

Shah et al, Nature Med 2023

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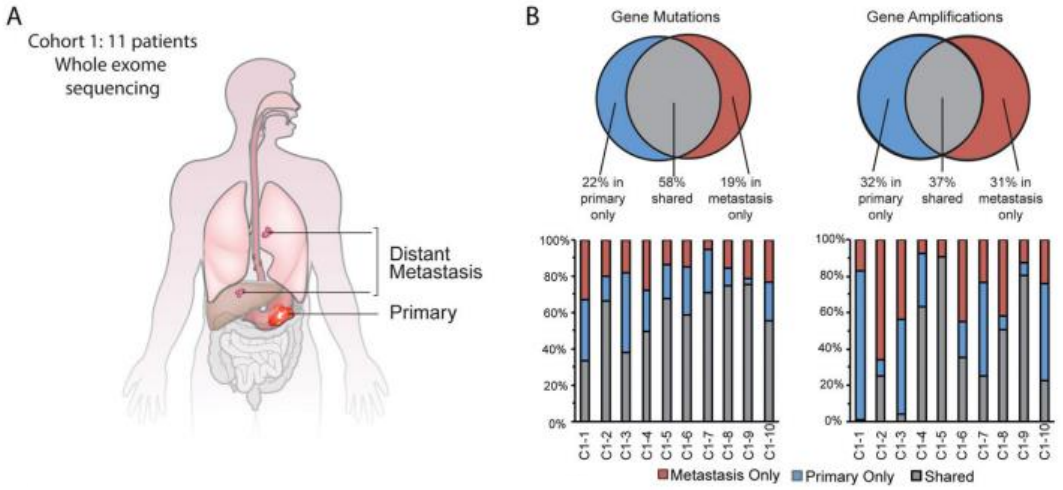
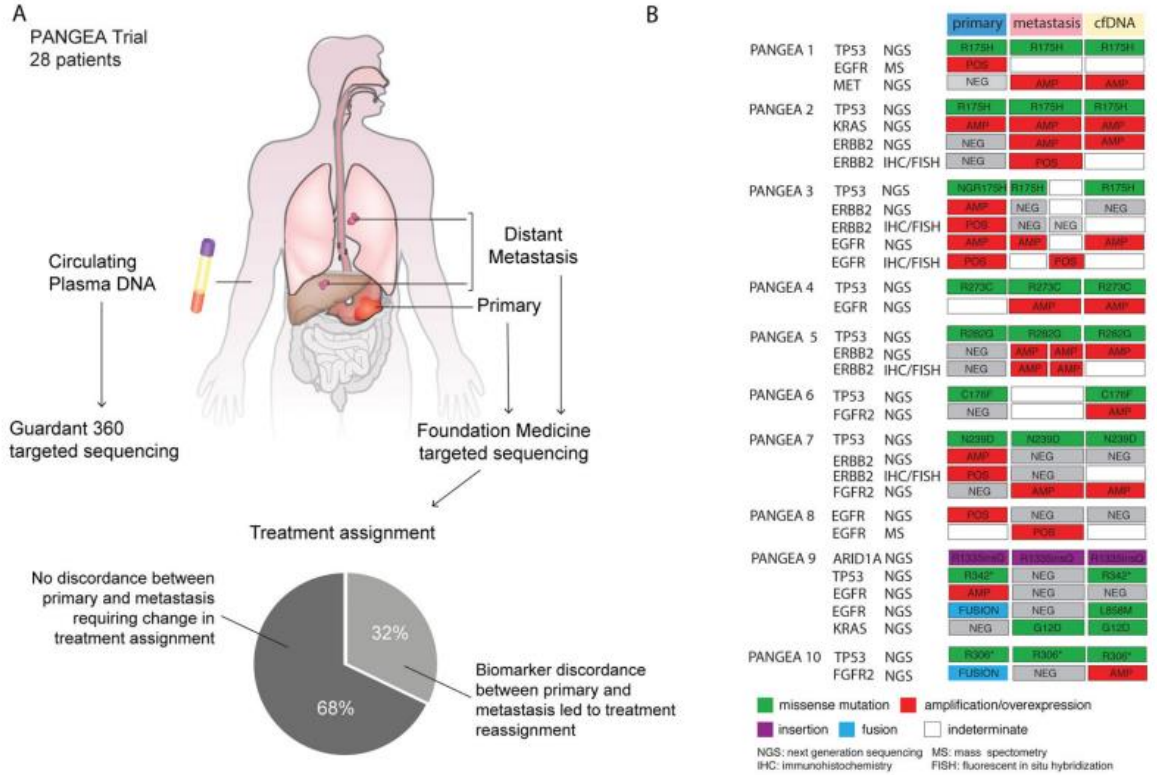
Barrieren für Präzisionsmedizin?

Genomische Heterogenität





Pectasides et al, Cancer Discovery 2018;8:1-12.

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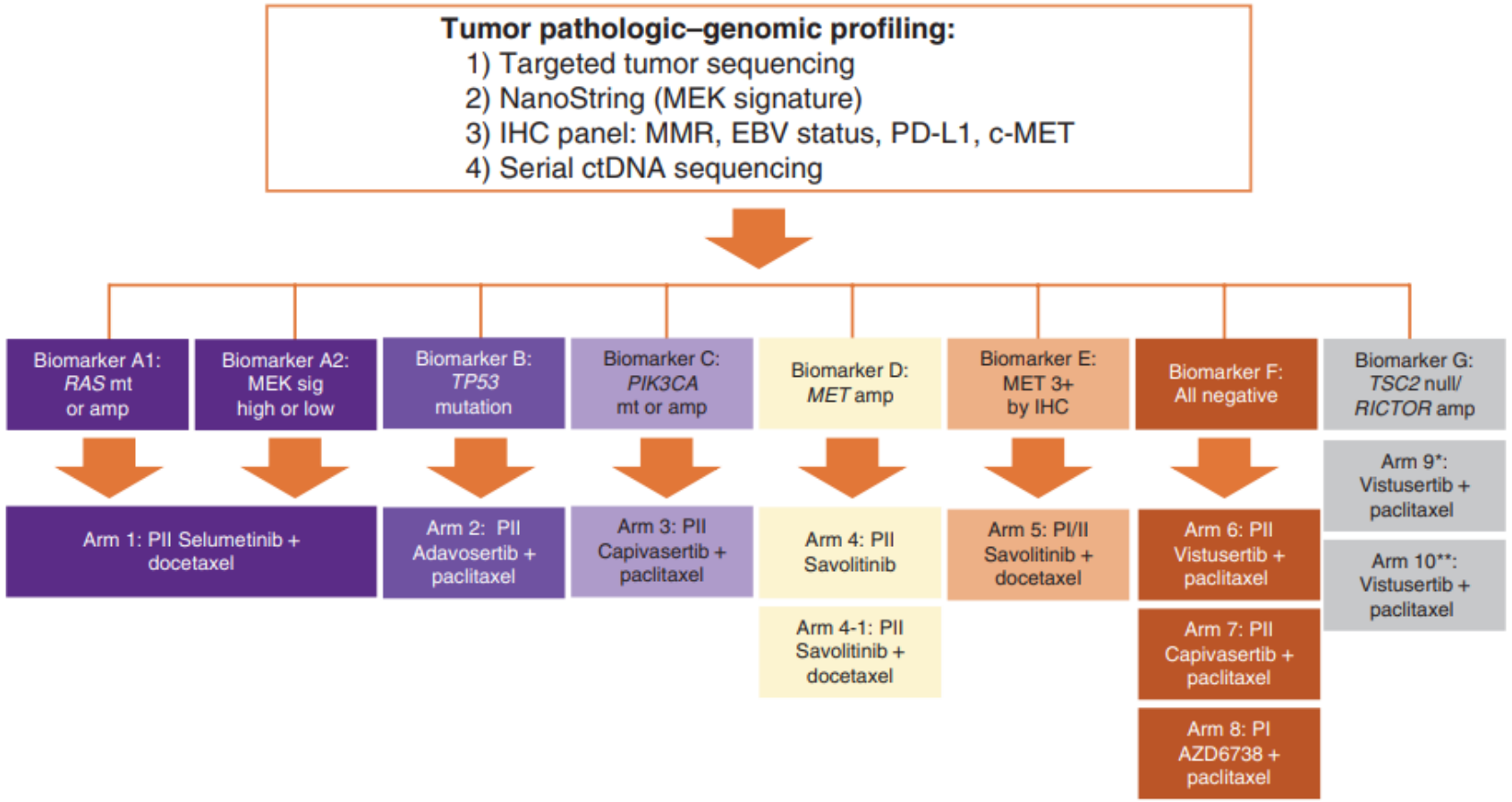
Präzisionstherapie: VICTORY Umbrella trial

Zukunft molekular definierter Studien?



Kim et al, Cancer Discovery 2019; 9:1388-1405.

Präzisionsonkologie perioperativ: Jetzt und in Zukunft

Fazit

- Präzisionsonkologie hat derzeit **keinen** etablierten Stellenwert in der perioperativen Therapie
- MMRd/MSI-H Patienten profitieren weniger von der Kombination Platin/5FU

  MMRd/MSI-H sprechen auf kombinierte Immuntherapie sehr gut an
- Her2-positive Patienten zeigen unter Trastuzumab + Chemo ein besseres Ansprechen

Präzisionsonkologie im perioperativen Setting: Jetzt und in Zukunft

Danke für Ihr Interesse!

Wolfgang Eisterer
Abteilung für Hämatologie und Internistische Onkologie

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