

# Inside the Issue: Integrating HER2-Targeted Strategies into the Management of Gastrointestinal Cancers

*A CME/MOC-Accredited Live Webinar*

**Wednesday, August 21, 2024**

**5:00 PM – 6:00 PM ET**

## **Faculty**

**Tanios Bekaii-Saab, MD**

**John Strickler, MD**

## **Moderator**

**Neil Love, MD**

# Faculty



**Tanios Bekaii-Saab, MD**

Professor, Mayo Clinic  
College of Medicine and Science  
Program Leader, Gastrointestinal Cancer  
Mayo Clinic Cancer Center  
Consultant, Mayo Clinic in Arizona  
Chair, ACCRU Research Consortium  
Phoenix, Arizona



**MODERATOR**

**Neil Love, MD**

Research To Practice  
Miami, Florida



**John Strickler, MD**

Professor of Medicine  
Associate Director, Clinical Research – GI  
Co-Leader, Molecular Tumor Board  
Duke University  
Durham, North Carolina

# Survey Participants



**Kristen K Ciombor, MD, MSCI**  
Associate Professor of Medicine  
Division of Hematology/Oncology  
Vanderbilt-Ingram Cancer Center  
Nashville, Tennessee



**Rutika Mehta, MD, MPH**  
Consultant  
New York, New York



**Christopher Lieu, MD**  
Professor of Medicine  
Associate Director for Clinical Research  
Co-Director, GI Medical Oncology  
University of Colorado Cancer Center  
Aurora, Colorado



**Philip A Philip, MD, PhD, FRCP**  
Professor of Oncology and Pharmacology  
Leader, GI and Neuroendocrine Oncology  
Henry Ford Cancer Institute  
Wayne State University  
Detroit, Michigan

## Commercial Support

This activity is supported by educational grants from AstraZeneca Pharmaceuticals LP and Daiichi Sankyo Inc.

## Dr Love — Disclosures

**Dr Love** is president and CEO of Research To Practice. Research To Practice receives funds in the form of educational grants to develop CME activities from the following companies: AbbVie Inc, Adaptive Biotechnologies Corporation, ADC Therapeutics, Agios Pharmaceuticals Inc, Alexion Pharmaceuticals, Amgen Inc, Array BioPharma Inc, a subsidiary of Pfizer Inc, Astellas, AstraZeneca Pharmaceuticals LP, Aveo Pharmaceuticals, Bayer HealthCare Pharmaceuticals, BeiGene Ltd, BeyondSpring Pharmaceuticals Inc, Blueprint Medicines, Boehringer Ingelheim Pharmaceuticals Inc, Bristol Myers Squibb, Celgene Corporation, Clovis Oncology, Coherus BioSciences, CTI BioPharma, a Sobi Company, Daiichi Sankyo Inc, Eisai Inc, Elevation Oncology Inc, EMD Serono Inc, Epizyme Inc, Exact Sciences Corporation, Exelixis Inc, Five Prime Therapeutics Inc, Foundation Medicine, G1 Therapeutics Inc, Genentech, a member of the Roche Group, Genmab US Inc, Geron Corporation, Gilead Sciences Inc, Grail Inc, GSK, Halozyme Inc, Helsinn Healthcare SA, ImmunoGen Inc, Incyte Corporation, Ipsen Biopharmaceuticals Inc, Janssen Biotech Inc, administered by Janssen Scientific Affairs LLC, Jazz Pharmaceuticals Inc, Karyopharm Therapeutics, Kite, A Gilead Company, Kronos Bio Inc, Legend Biotech, Lilly, Loxo Oncology Inc, a wholly owned subsidiary of Eli Lilly & Company, MEI Pharma Inc, Merck, Mersana Therapeutics Inc, Mirati Therapeutics Inc, Mural Oncology Inc, Natera Inc, Novartis, Novartis Pharmaceuticals Corporation on behalf of Advanced Accelerator Applications, Novocure Inc, Oncoceptides, Pfizer Inc, Pharmacyclics LLC, an AbbVie Company, Puma Biotechnology Inc, Regeneron Pharmaceuticals Inc, R-Pharm US, Sanofi, Seagen Inc, Servier Pharmaceuticals LLC, SpringWorks Therapeutics Inc, Stemline Therapeutics Inc, Sumitomo Dainippon Pharma Oncology Inc, Syndax Pharmaceuticals, Taiho Oncology Inc, Takeda Pharmaceuticals USA Inc, TerSera Therapeutics LLC, Tesaro, A GSK Company, TG Therapeutics Inc, Turning Point Therapeutics Inc, Verastem Inc, and Zymeworks Inc.

# Research To Practice CME Planning Committee Members, Staff and Reviewers

Planners, scientific staff and independent reviewers for Research To Practice have no relevant conflicts of interest to disclose.

# Dr Bekai-Saab — Disclosures

## Faculty

<b>Consulting Agreements (to Institution)</b>	Arcus Biosciences, Bayer HealthCare Pharmaceuticals, Eisai Inc, Genentech, a member of the Roche Group, Incyte Corporation, Ipsen Biopharmaceuticals Inc, Merck, Merck KGaA, Merus, Pfizer Inc, Seagen Inc, Servier Pharmaceuticals LLC
<b>Consulting Agreements (to Self)</b>	AbbVie Inc, Aptitude Health, AstraZeneca Pharmaceuticals LP, BeiGene Ltd, Blueprint Medicines, Boehringer Ingelheim Pharmaceuticals Inc, Caladrius Biosciences, Celularity, Daiichi Sankyo Inc, Deciphera Pharmaceuticals Inc, Exact Sciences Corporation, Exelixis Inc, Foundation Medicine, GSK, Illumina, Janssen Biotech Inc, Kanaph Therapeutics, Natera Inc, Sanofi, Sobi, Stemline Therapeutics Inc, Treos Bio Ltd, Zai Lab
<b>Data and Safety Monitoring Boards/Committees</b>	1Globe Health Institute, AstraZeneca Pharmaceuticals LP, Eisai Inc, Exelixis Inc, FibroGen Inc, Merck, Suzhou Kintor
<b>Inventions/Patents</b>	WO/2018/183488 licensed to Imugene, WO/2019/055687 licensed to Recursion
<b>Research Funding (to Institution)</b>	AbGenomics, Agios Pharmaceuticals Inc, Arcus Biosciences, Arrys Therapeutics, a wholly owned subsidiary of Kyn Therapeutics, Atreca, Bayer HealthCare Pharmaceuticals, Bristol Myers Squibb, Celgene Corporation, Clovis Oncology, Eisai Inc, Genentech, a member of the Roche Group, Incyte Corporation, Ipsen Biopharmaceuticals Inc, Lilly, Merus, Mirati Therapeutics Inc, Novartis, Pfizer Inc, Seagen Inc, Sumitomo Dainippon Pharma Oncology Inc
<b>Scientific Advisory Boards</b>	Artiva Biotherapeutics Inc, Immuneering Corporation, Imugene, Panbela Therapeutics Inc, Replimune, Xilis
<b>Nonrelevant Financial Relationships</b>	MJH Life Sciences, Pancreatic Cancer Action Network, The Valley Hospital, UptoDate

# Dr Strickler — Disclosures Faculty

<b>Advisory Committees</b>	AbbVie Inc, Astellas, AstraZeneca Pharmaceuticals LP, Bayer HealthCare Pharmaceuticals, BeiGene Ltd, Daiichi Sankyo Inc, GE Healthcare, Genentech, a member of the Roche Group, GSK, Jazz Pharmaceuticals Inc, Johnson & Johnson Pharmaceuticals, Lilly, Merck, Natera Inc, Pfizer Inc, Regeneron Pharmaceuticals Inc, Sanofi, Taiho Oncology Inc, Takeda Pharmaceuticals USA Inc, Xilio Therapeutics
<b>Contracted Research</b>	AbbVie Inc, Amgen Inc, A*STAR D3, Bayer HealthCare Pharmaceuticals, BeiGene Ltd, Curegenix Inc, Daiichi Sankyo Inc, Erasca, Genentech, a member of the Roche Group, GSK, Leap Therapeutics Inc, Lilly, Novartis, Pfizer Inc, Quanta Therapeutics, Revolution Medicines
<b>Data and Safety Monitoring Boards/Committees</b>	AbbVie Inc, Astellas, BeiGene Ltd, GSK, Pfizer Inc
<b>Stock Options — Private Company</b>	Triumvira Immunologics



# Dr Ciombor — Disclosures

## Survey Participant

<b>Advisory Committees</b>	Agenus Inc, ALX Oncology, Bayer HealthCare Pharmaceuticals, Exelixis Inc, Incyte Corporation, Merck, Personalis, Pfizer Inc, Replimune, Seagen Inc, Taiho Oncology Inc, Tempus
<b>Consulting Agreements</b>	Merck, Pfizer Inc
<b>Contracted Research</b>	Array BioPharma Inc, a subsidiary of Pfizer Inc, Bristol Myers Squibb, Calithera Biosciences, Daiichi Sankyo Inc, Genentech, a member of the Roche Group, Incyte Corporation, Merck, NuCana, Pfizer Inc, Seagen Inc

# Dr Lieu — Disclosures Survey Participant

No relevant conflicts of interest to disclose.

# Dr Mehta — Disclosures Survey Participant

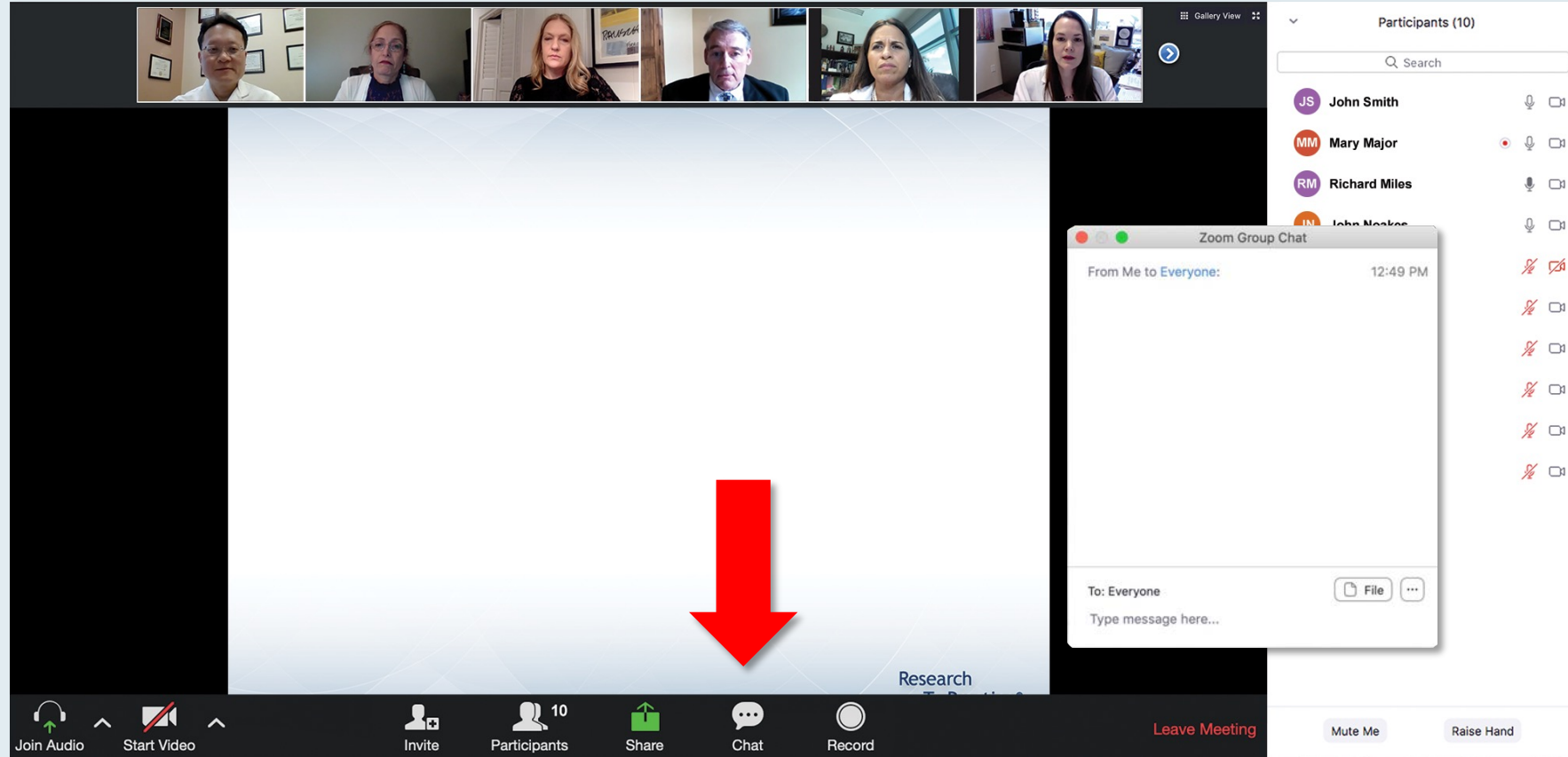
<b>Advisory Committees</b>	Astellas, BostonGene, Bristol Myers Squibb, Eisai Inc, Guardant Health, Lilly, Merck, Natera Inc, Novartis, Seagen Inc
<b>Consulting Agreement</b>	Lilly
<b>Data and Safety Monitoring Board/Committee</b>	Arcus Biosciences

# Dr Philip — Disclosures Survey Participant

<b>Advisory Committees</b>	Agenus Inc, Ipsen Biopharmaceuticals Inc, Merus, Novocure Inc
<b>Consulting Agreement</b>	Novocure Inc
<b>Contracted Research</b>	BioNTech SE, Cornerstone Pharmaceuticals Inc, Taiho Oncology Inc, Totus Medicines Inc
<b>Data and Safety Monitoring Board/Committee</b>	Cyclacel Pharmaceuticals Inc
<b>Speakers Bureaus</b>	Astellas, Incyte Corporation

**This educational activity contains discussion of non-FDA-approved uses of agents and regimens. Please refer to official prescribing information for each product for approved indications.**

# We Encourage Clinicians in Practice to Submit Questions



Feel free to submit questions now before the program begins and throughout the program.

# Familiarizing Yourself with the Zoom Interface

## Expand chat submission box

The screenshot shows a Zoom meeting interface. At the top, there are video thumbnails for participants: RTP Coordinat..., Kirsten Miller, RTP Mike Rivera, and Lisa Suarez. Below the thumbnails is a slide titled "Meet The Professor Program Participating Faculty" with six faculty members listed:

- Nancy L Bartlett, MD**  
Professor of Medicine  
Koman Chair in Medical Oncology  
Washington University School of Medicine  
St Louis, Missouri
- Jonathan W Friedberg, MD, MMSc**  
Samuel E Durand Professor of Medicine  
Director, James P Wilmot Cancer Institute  
University of Rochester  
Rochester, New York
- Carla Casulo, MD**  
Associate Professor of Medicine  
Division of Hematology/Oncology  
Director, Hematology/Oncology Fellowship Program  
University of Rochester  
Wilmot Cancer Institute  
Rochester, New York
- Brian T Hill, MD, PhD**  
Director, Lymphoid Malignancy Program  
Cleveland Clinic Taussig Cancer Institute  
Cleveland, Ohio
- Christopher R Flowers, MD, MS**  
Chair, Professor  
Department of Lymphoma/Myeloma  
The University of Texas MD Anderson Cancer Center  
Houston, Texas
- Brad S Kahl, MD**  
Professor of Medicine  
Washington University School of Medicine  
Director, Lymphoma Program  
Siteman Cancer Center  
St Louis, Missouri

The chat window on the right shows a message from "Me to Panelists" at 4:31 PM with a link to a PDF slide. Below it is a message from "Me to Panelists and Attendees" at 4:32 PM with the same link. At the bottom of the chat window, there is a dropdown menu set to "Panelists and Attendees" and a text input field "Type message here...". A red arrow points to the white line above the input field, indicating how to expand the chat box.

Drag the white line above the submission box up to create more space for your message.

# Familiarizing Yourself with the Zoom Interface

## Increase chat font size



The screenshot displays a Zoom meeting interface. At the top, there are video thumbnails for participants: RTP Coordinator, Kirsten Miller, RTP Mike Rivera, and Lisa Suarez. The main content area shows a slide titled "Research To Practice CME Planning Committee Members, Staff and Reviewers" with the text: "Planners, scientific staff and independent reviewers for Research To Practice have no relevant conflicts of interest to disclose." On the right, the chat window is open, showing a message from "Me to Panelists" with a link to a PDF document. A red arrow points to the font size adjustment icon (a plus sign) in the chat window's header area.

**Press Command (for Mac) or Control (for PC) and the + symbol.  
You may do this as many times as you need for readability.**



# Clinicians in the Audience, Please Complete the Pre- and Postmeeting Surveys

The screenshot shows a Zoom meeting with a presentation slide on the left and a 'Quick Survey' overlay on the right. The slide text reads: 'Meet The Prof...', 'Optimizing the Selection and...', 'of Therapy for Patients with...', 'Gastrointestinal Ca...', 'Wednesday, August 25, 5:00 PM – 6:00 PM E...', 'Faculty Wells A Messersmith, Moderator Neil Love, MD'. The survey overlay lists several treatment combinations with radio buttons for selection: 'Carfilzomib +/- dexamethasone', 'Pomalidomide +/- dexamethasone', 'Carfilzomib + pomalidomide +/- dexamethasone', 'Eltuzumab + lenalidomide +/- dexamethasone', 'Eltuzumab + pomalidomide +/- dexamethasone', 'Daratumumab + lenalidomide +/- dexamethasone', 'Daratumumab + pomalidomide +/- dexamethasone', 'Daratumumab + bortezomib +/- dexamethasone', and 'Ixazomib + Rd'. A 'Submit' button is at the bottom of the survey. The Zoom interface includes a top video gallery, a 'Participants (10)' list on the right, and a bottom toolbar with 'Join Audio', 'Start Video', 'Invite', 'Participants', 'Share', 'Chat', 'Record', 'Leave Meeting', 'Mute Me', and 'Raise Hand'.

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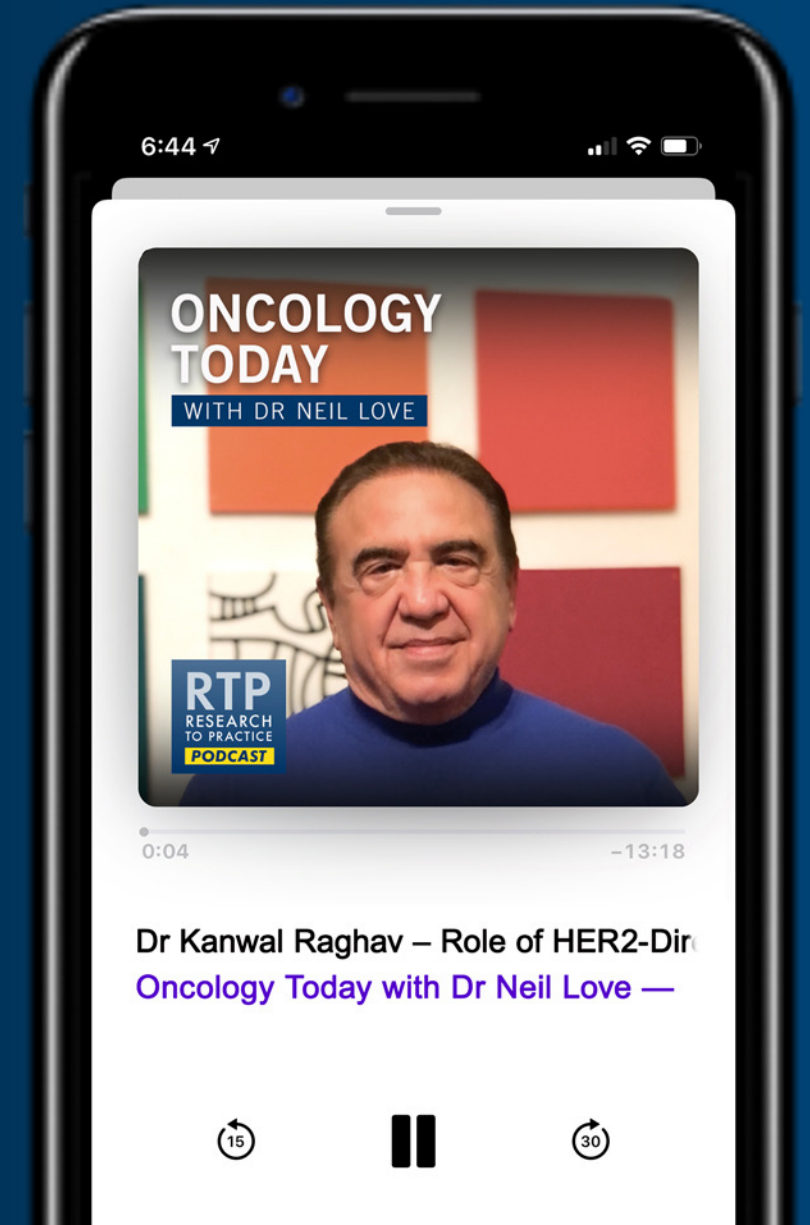
# ONCOLOGY TODAY

WITH DR NEIL LOVE

## Role of HER2-Directed Therapy in the Treatment of HER2-Expressing Gastrointestinal Cancers — Part 2 of a Special 3-Part Edition



**DR KANWAL RAGHAV**  
THE UNIVERSITY OF TEXAS  
MD ANDERSON CANCER CENTER



# Inside the Issue: Optimizing the Diagnosis and Treatment of Neuroendocrine Tumors

*A CME/MOC-Accredited Live Webinar*

**Thursday, August 29, 2024**

**5:00 PM – 6:00 PM ET**

## **Faculty**

**Pamela Kunz, MD**

**Simron Singh, MD, MPH**

## **Moderator**

**Neil Love, MD**

# Data + Perspectives: Clinical Investigators Discuss the Role of CAR T-Cell Therapy for Patients with Non-Hodgkin Lymphoma and Chronic Lymphocytic Leukemia

*Part 1 of a 2-Part CME Satellite Symposium Series During the  
Society of Hematologic Oncology 2024 Annual Meeting*

**Wednesday, September 4, 2024**

**11:46 AM – 12:46 PM CT**

## **Faculty**

**Joshua Brody, MD**

**Jason Westin, MD, MS**

## **Moderator**

**Matthew Lunning, DO**

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**Christopher R Flowers, MD, MS**

# Meet The Professor: Optimizing the Management of Chronic Lymphocytic Leukemia

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**Tuesday, September 17, 2024**

**5:00 PM – 6:00 PM ET**

## **Faculty**

**Matthew S Davids, MD, MMSc**

## **Moderator**

**Neil Love, MD**

# What Clinicians Want to Know: Addressing Current Questions and Controversies in the Management of Hematologic Cancers

*A CME Hybrid Friday Satellite Symposium Series Preceding  
the 66<sup>th</sup> ASH Annual Meeting and Exposition*

**Friday, December 6, 2024**

**Chronic Myeloid Leukemia**

**7:30 AM – 9:00 AM PT**

**Chronic Lymphocytic Leukemia**

**7:30 AM – 9:30 AM PT**

**CAR T-Cell Therapy**

**11:30 AM – 1:30 PM PT**

**Myelofibrosis**

**11:30 AM – 1:30 PM PT**

**Acute Myeloid Leukemia**

**3:15 PM – 5:15 PM PT**

**Multiple Myeloma**

**3:15 PM – 5:15 PM PT**

# What Clinicians Want to Know: Addressing Current Questions and Controversies in the Management of Chronic Myeloid Leukemia

*A CME Friday Satellite Symposium and Webcast Preceding the 66<sup>th</sup> ASH Annual Meeting*

**Friday, December 6, 2024**

**7:30 AM – 9:00 AM PT (10:30 AM – 12:00 PM ET)**

## **Faculty**

**Andreas Hochhaus, MD**

**B Douglas Smith, MD**

## **Moderator**

**Michael J Mauro, MD**



# What Clinicians Want to Know: Addressing Current Questions and Controversies in the Management of Chronic Lymphocytic Leukemia

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**Friday, December 6, 2024**

**7:30 AM – 9:30 AM PT (10:30 AM – 12:30 PM ET)**

## **Faculty**

**Farrukh T Awan, MD, MS, MBA**

**Bitra Fakhri, MD, MPH**

**Kerry A Rogers, MD**

**William G Wierda, MD, PhD**

## **Moderator**

**Jeff Sharman, MD**

# What Clinicians Want to Know: Addressing Current Questions and Controversies in the Use of CAR T-Cell Therapy and Bispecific Antibodies in the Management of Lymphoma

*A CME Friday Satellite Symposium and Webcast Preceding the 66<sup>th</sup> ASH Annual Meeting*

**Friday, December 6, 2024**

**11:30 AM – 1:30 PM PT (2:30 PM – 4:30 PM ET)**

## **Faculty**

**Jennifer Crombie, MD**

**Matthew Lunning, DO**

**Martin Hutchings, MD, PhD**

**Tysel Phillips, MD**

## **Moderator**

**Jeremy S Abramson, MD, MMSc**

# What Clinicians Want to Know: Addressing Current Questions and Controversies in the Management of Myelofibrosis

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**Friday, December 6, 2024**

**11:30 AM – 1:30 PM PT (2:30 PM – 4:30 PM ET)**

## **Faculty**

**Prithviraj Bose, MD**

**Abdulraheem Yacoub, MD**

*Additional faculty to be announced.*

## **Moderator**

**Andrew T Kuykendall, MD**

# What Clinicians Want to Know: Addressing Current Questions and Controversies in the Management of Acute Myeloid Leukemia

*A CME Friday Satellite Symposium and Webcast Preceding the 66<sup>th</sup> ASH Annual Meeting*

**Friday, December 6, 2024**

**3:15 PM – 5:15 PM PT (6:15 PM – 8:15 PM ET)**

## **Faculty**

**Alexander Perl, MD**  
**Richard M Stone, MD**

**Eunice S Wang, MD**  
**Andrew H Wei, MBBS, PhD**

## **Moderator**

**Eytan M Stein, MD**

# What Clinicians Want to Know: Addressing Current Questions and Controversies in the Management of Multiple Myeloma

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**Friday, December 6, 2024**

**3:15 PM – 5:15 PM PT (6:15 PM – 8:15 PM ET)**

## **Faculty**

**Professor Philippe Moreau, MD**

**Robert Z Orlowski, MD, PhD**

**Noopur Raje, MD**

**Paul G Richardson, MD**

## **Moderator**

**Sagar Lonial, MD**

***Thank you for joining us!***

***Information on how to obtain CME, ABIM MOC  
and ABS credit will be provided at the  
conclusion of the activity in the Zoom chat room.***

***Attendees will also receive an email in  
1 to 3 business days with these instructions.***

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New York, New York

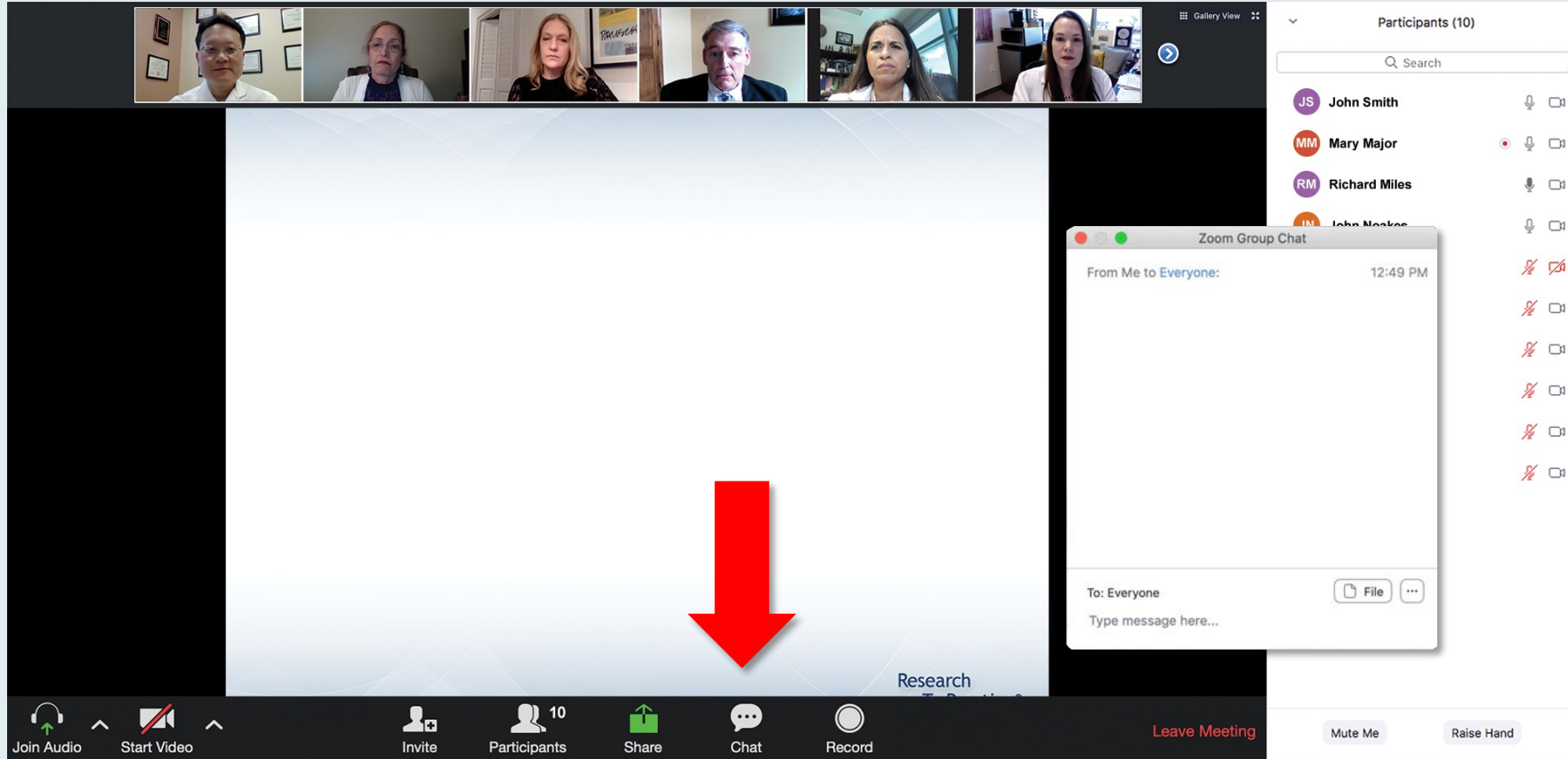


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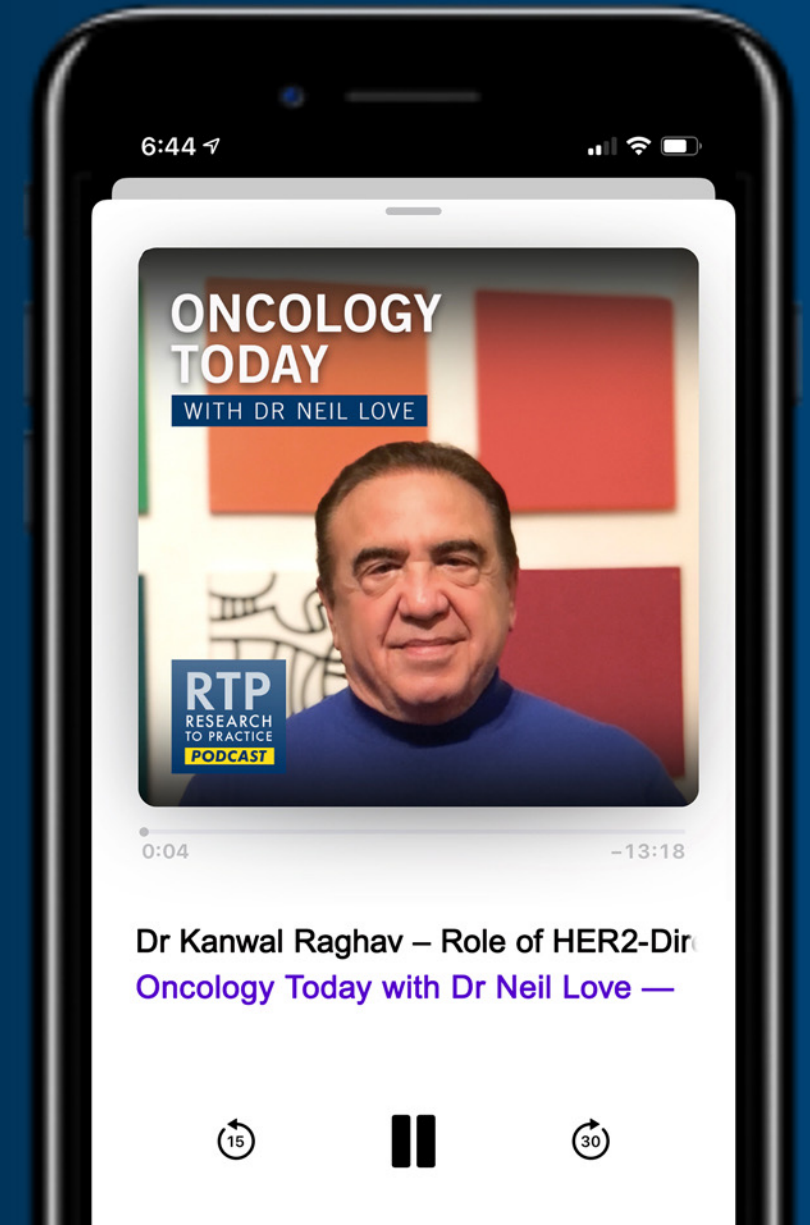
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# Dr Bekai-Saab — Disclosures

## Faculty

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<b>Data and Safety Monitoring Boards/Committees</b>	1Globe Health Institute, AstraZeneca Pharmaceuticals LP, Eisai Inc, Exelixis Inc, FibroGen Inc, Merck, Suzhou Kintor
<b>Inventions/Patents</b>	WO/2018/183488 licensed to Imugene, WO/2019/055687 licensed to Recursion
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# Dr Strickler — Disclosures

## Faculty

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# Dr Ciombor — Disclosures

## Survey Participant

<b>Advisory Committees</b>	Agenus Inc, ALX Oncology, Bayer HealthCare Pharmaceuticals, Exelixis Inc, Incyte Corporation, Merck, Personalis, Pfizer Inc, Replimune, Seagen Inc, Taiho Oncology Inc, Tempus
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# Dr Lieu — Disclosures Survey Participant

No relevant conflicts of interest to disclose.

# Dr Mehta — Disclosures Survey Participant

<b>Advisory Committees</b>	Astellas, BostonGene, Bristol Myers Squibb, Eisai Inc, Guardant Health, Lilly, Merck, Natera Inc, Novartis, Seagen Inc
<b>Consulting Agreement</b>	Lilly
<b>Data and Safety Monitoring Board/Committee</b>	Arcus Biosciences

# Dr Philip — Disclosures Survey Participant

<b>Advisory Committees</b>	Agenus Inc, Ipsen Biopharmaceuticals Inc, Merus, Novocure Inc
<b>Consulting Agreement</b>	Novocure Inc
<b>Contracted Research</b>	BioNTech SE, Cornerstone Pharmaceuticals Inc, Taiho Oncology Inc, Totus Medicines Inc
<b>Data and Safety Monitoring Board/Committee</b>	Cyclacel Pharmaceuticals Inc
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## Dr Love — Disclosures

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**This educational activity contains discussion of non-FDA-approved uses of agents and regimens. Please refer to official prescribing information for each product for approved indications.**

# HER2-Targeted Strategies for HER2+ Gastroesophageal and Colorectal Cancer

John H. Strickler, MD  
Professor of Medicine  
Duke University Medical Center

August 20, 2024

Duke UNIVERSITY



## Emerging Role of HER2-Targeted Therapy in Advanced Biliary Tract Cancers (BTCs)

**Tanios Bekaii-Saab, MD**

David F. and Margaret T. Grohne Professor of Novel Therapeutics for Cancer Research I  
Chair and Consultant, Division of Hematology and Medical Oncology  
Professor, Mayo Clinic College of Medicine and Science  
Mayo Clinic in Arizona



# Agenda

**Introduction: Back to School Special**

**Module 1: Biomarker Assays in Advanced Gastrointestinal (GI) Cancers**

**Module 2: Sequencing of Treatment for HER2-Positive GI Cancers**

- Colorectal Cancer
- Gastroesophageal Cancer
- Biliary Tract Cancer

**Module 3: Toxicities Associated with Anti-HER2 Treatment**

**Module 4: Novel Agents and Strategies for HER2-Positive GI Cancers**





ESPN  
**PARDON  
THE  
INTERRUPTION**

**PTI**  
PTI



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FIRST DAY OF

PRE-K

Today is

8/19/24

When I grow up I want to be

Astronaut

KIM YEARS OLD

4

I LOVE TO

Dance

MY FAVORITES:

Color Pink Purple Children's Hobby color



**How many of your family (children, grandchildren, nieces, nephews, other loved ones) have returned or are about to return to school at any level (PreK-12 and beyond)?**

**What are the ages and grade levels of your family members who are returning to school?**



**JESSICA MITCHELL, APRN, CNP, MPH**

MAYO CLINIC COLLEGE OF  
MEDICINE AND SCIENCE  
ROCHESTER, MINNESOTA

**INCLUDING CHILDREN IN THE CANCER JOURNEY  
OF THEIR PARENT**

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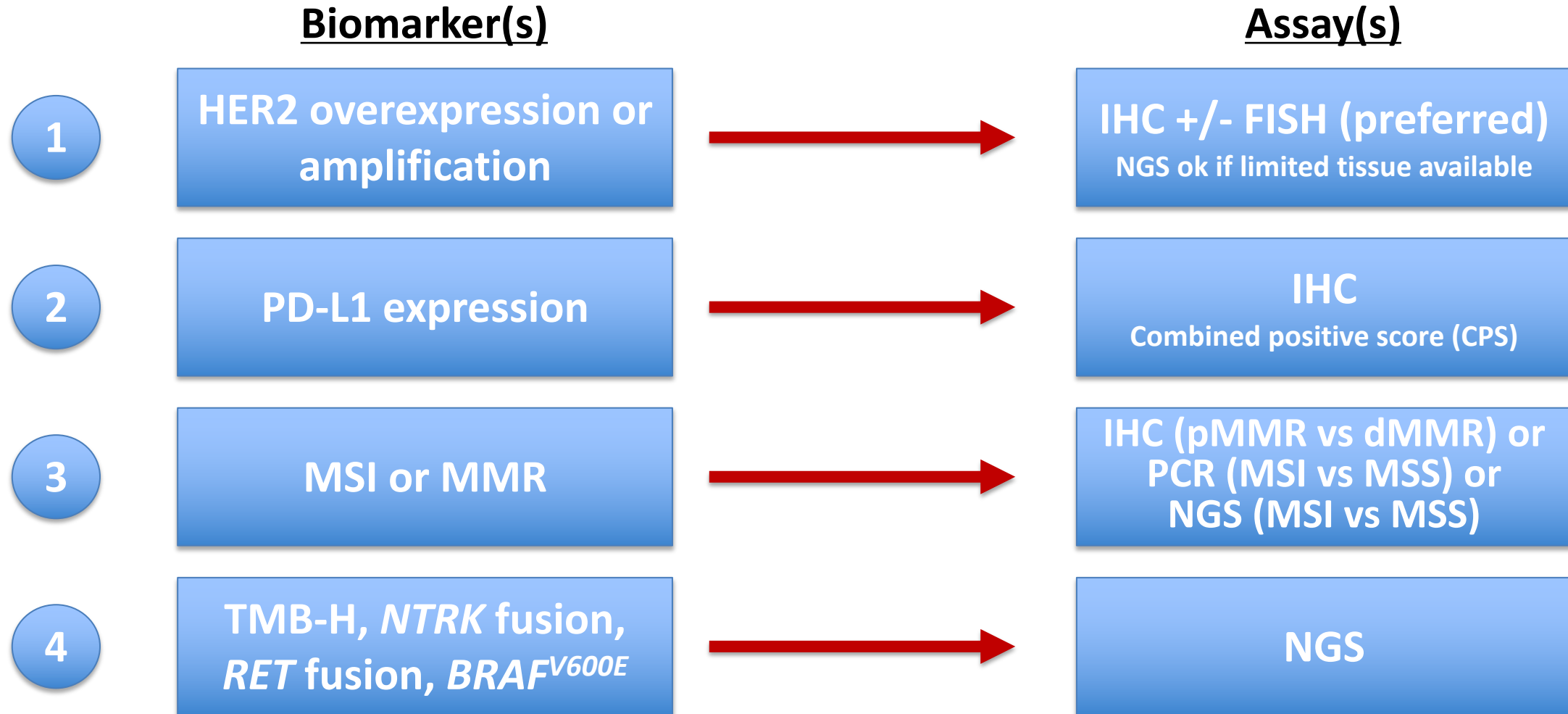
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# Biomarkers for metastatic gastric/gastroesophageal cancer

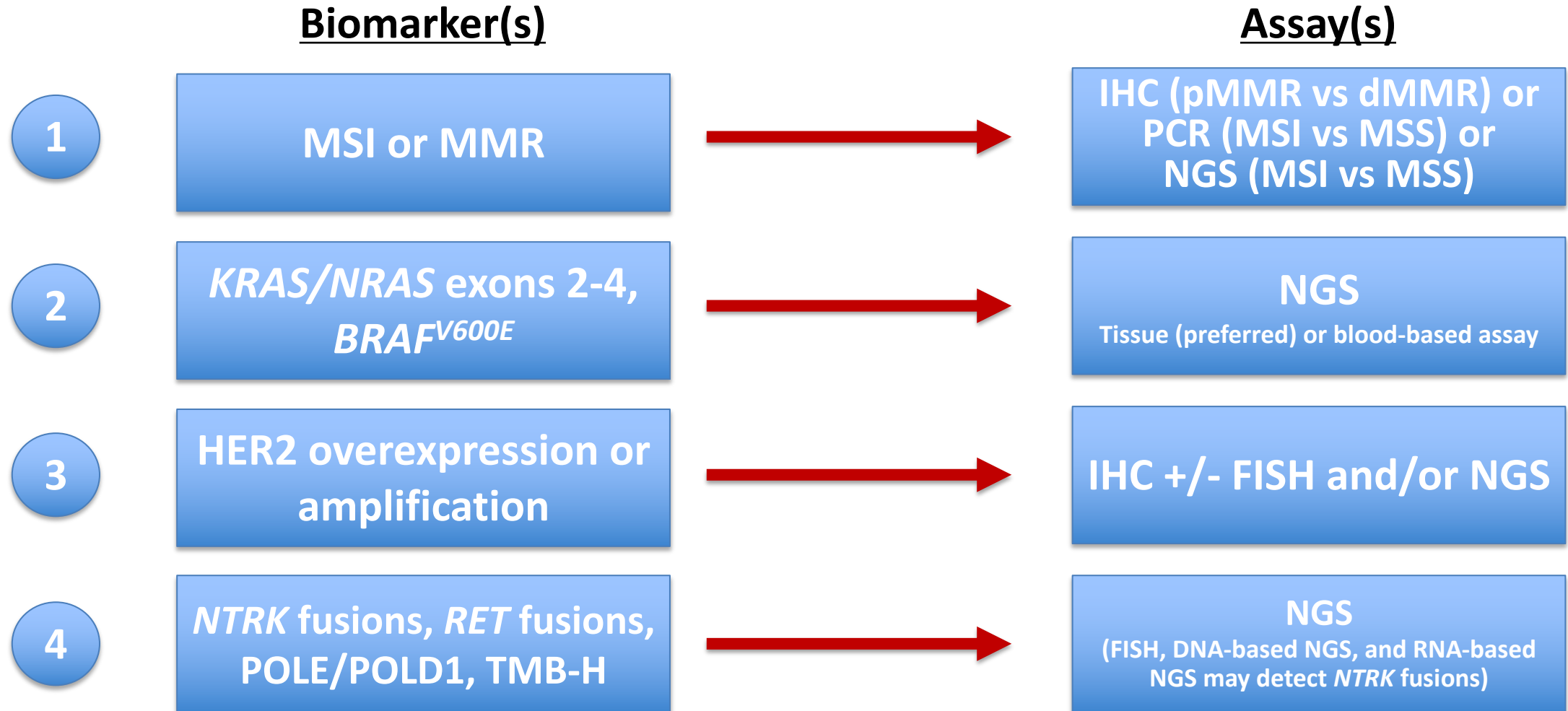
(NCCN v3.2024)



**Other tests to consider:** Blood NGS “liquid biopsy,” germline testing, tumor EBV, claudin 18.2, WES/ WTS

# Biomarkers for metastatic colon cancer

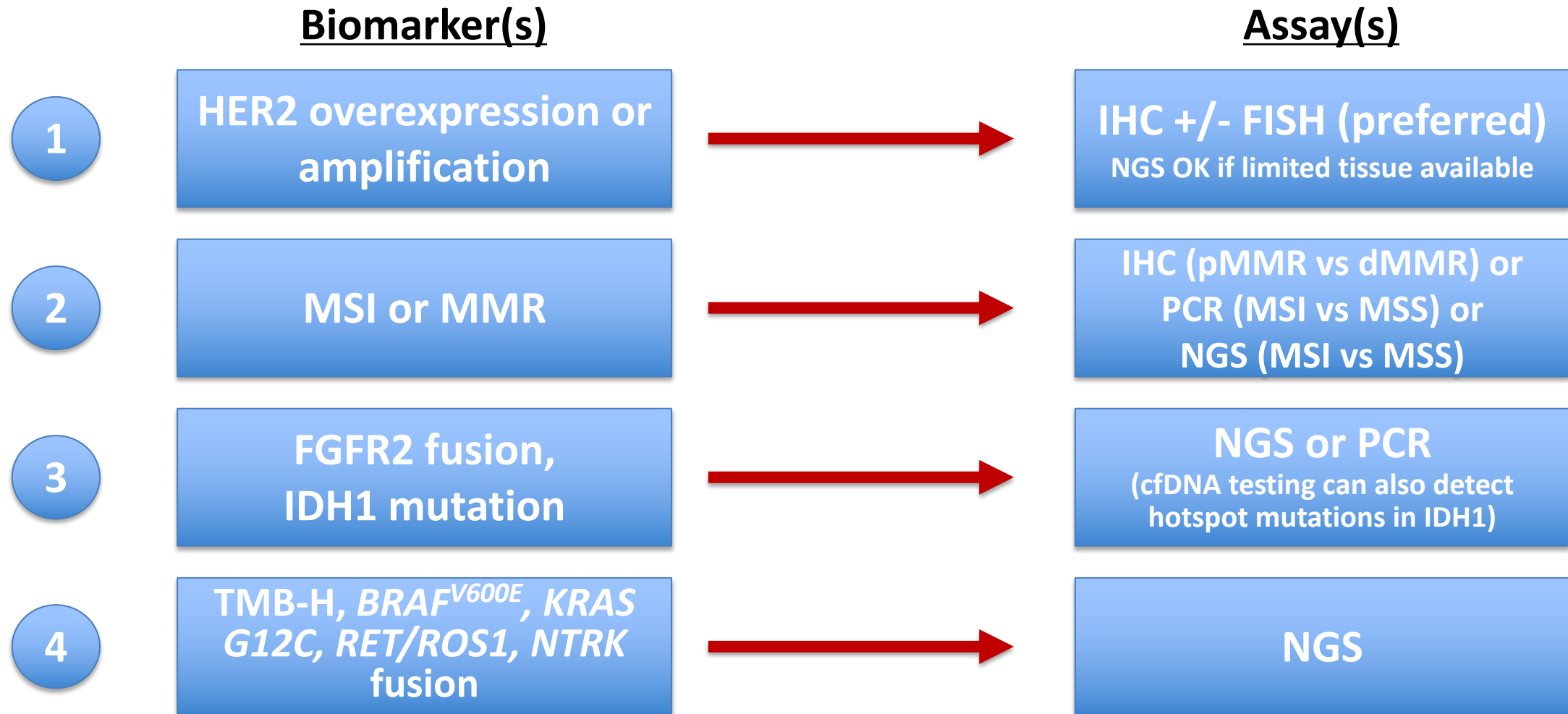
(NCCN v4.2024)









**Other tests to consider:** Blood NGS after progression on targeted therapy, germline testing, RNA seq, WES/WTS

# Biomarkers for metastatic biliary tract cancers

(NCCN v3.2024)









## In general, what is your threshold for HER2 amplification to initiate anti-HER2 treatment?

	Colorectal cancer	Gastroesophageal cancer	Biliary tract cancers
 Dr Bekaii-Saab	HER2/CEP17 ratio $\geq 2.0$ or HER2 copy number $\geq 6$	HER2/CEP17 ratio $\geq 2.0$ or HER2 copy number $\geq 6$	HER2/CEP17 ratio $\geq 2.0$ or HER2 copy number $\geq 6$
 Dr Strickler	Amplified by NGS	IHC 3+ or IHC 2+/FISH amplified	IHC 3+ or amplified by NGS
 Dr Ciombor	IHC 3+, IHC 2+/FISH or ERBB2 amplified	IHC 3+, IHC 2+/FISH or ERBB2 amplified	IHC 3+, IHC 2+/FISH or ERBB2 amplified
 Dr Lieu	IHC 3+ or IHC 2+/FISH amplified	IHC 3+ or IHC 2+/FISH amplified	IHC 3+ or IHC 2+/FISH amplified
 Dr Mehta	2+	2+	Copy number $\geq 4$ with liquid biopsy
 Dr Philip	$>2$	$>2$	$>2$

NGS = next-generation sequencing; IHC = immunohistochemistry; FISH = fluorescence in situ hybridization

## Does RAS status (KRAS, BRAF) factor into your decision about which anti-HER2 treatment to administer to a patient with advanced HER2-positive GI cancer?

	Colorectal cancer	Gastroesophageal cancer	Biliary tract cancers
 Dr Bekaii-Saab	Both	Neither	Both
 Dr Strickler	Both	Neither	Both
 Dr Ciombor	Both	Both	Both
 Dr Lieu	KRAS	Neither	Neither
 Dr Mehta	KRAS	Neither	KRAS
 Dr Philip	Neither	Neither	Neither



# Case Presentation – Dr Strickler: 70-Year-Old Woman with HER2-Positive Colon Cancer

- Adenocarcinoma of splenic flexure found on routine screening colonoscopy
  - CT scan: large mass in descending colon, multifocal unresectable hepatic metastases
  - Biopsy confirms metastatic adenocarcinoma consistent with colorectal primary
- Genomic profile: MSS, TMB-low, *RAS/BRAF* wildtype, *TP53* mutation, HER2 IHC 3+; *ERBB2* amplified
- Seeking 2nd opinion after PD on FOLFIRI/bevacizumab and FOLFOX/bevacizumab
- Tucatinib + trastuzumab with PR; PD in the liver after 14 months
- Liquid biopsy after progression: MSS, TMB-low, *RAS/BRAF* wildtype, *TP53* and *APC* mutations, *ERBB2* amplified (high +++), *MET* amplified (medium ++)
- Trastuzumab deruxtecan – remains on treatment over 3 years

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- Biliary Tract Cancer







**Module 3: Toxicities Associated with Anti-HER2 Treatment**

**Module 4: Novel Agents and Strategies for HER2-Positive GI Cancers**

In general, at what point do you administer anti-HER2 treatment to patients with HER2-positive colorectal, gastroesophageal or biliary tract cancer?

	Colorectal cancer	Gastroesophageal cancer	Biliary tract cancers
 <b>Dr Bekaii-Saab</b>	Second-line metastatic disease	First-line metastatic disease	Second-line metastatic disease
 <b>Dr Strickler</b>	Second-line metastatic disease	First-line metastatic disease	Second-line metastatic disease
 <b>Dr Ciombor</b>	Second- or third-line metastatic disease	First-line metastatic disease	Second-line metastatic disease
 <b>Dr Lieu</b>	Second-line metastatic disease	First-line metastatic disease	Second-line metastatic disease
 <b>Dr Mehta</b>	Second- or third-line metastatic disease	First-, second- or third-line metastatic disease	Second-line and beyond
 <b>Dr Philip</b>	Second-line metastatic disease	First-line metastatic disease	Second-line metastatic disease

Regulatory and reimbursement issues aside, at what point would you like to administer anti-HER2 treatment for patients with HER2-positive disease?

	Colorectal cancer	Gastroesophageal cancer	Biliary tract cancers
 Dr Bekaii-Saab	First-line metastatic disease	First-line metastatic disease	First-line metastatic disease
 Dr Strickler	First-line metastatic disease	First-line metastatic disease	First-line metastatic disease
 Dr Ciombor	First-line metastatic disease	First-line metastatic disease	First- or second-line metastatic disease
 Dr Lieu	Second-line metastatic disease	First-line metastatic disease	Second-line metastatic disease
 Dr Mehta	Second-line metastatic disease	First-line metastatic disease	Second-line metastatic disease
 Dr Philip	Second-line metastatic disease	First-line metastatic disease	First-line metastatic disease

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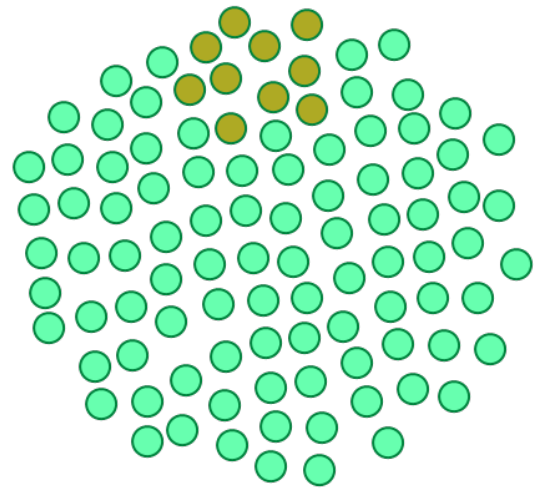
**Module 3: Toxicities Associated with Anti-HER2 Treatment**

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# HER2 IHC criteria for HER2+

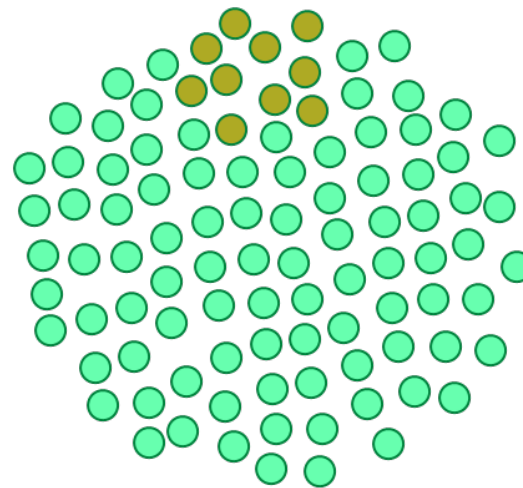
## Breast

- IHC 3+
- IHC 2+ and ISH amplification
- In  $\geq 10\%$  tumor cells



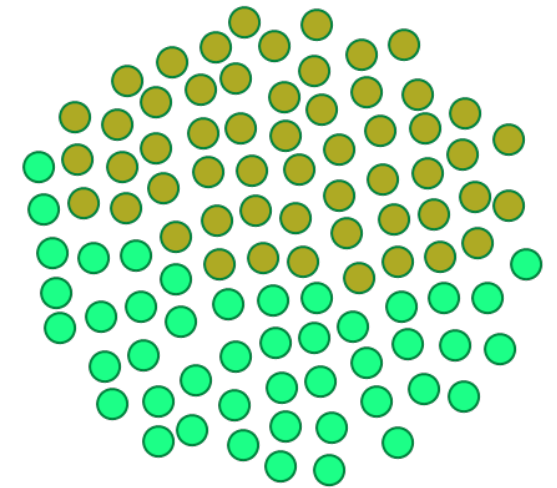
## Gastric

- IHC 3+
- IHC 2+ and ISH amplification
- In  $\geq 10\%$  tumor cells



## HERACLES<sup>1</sup>

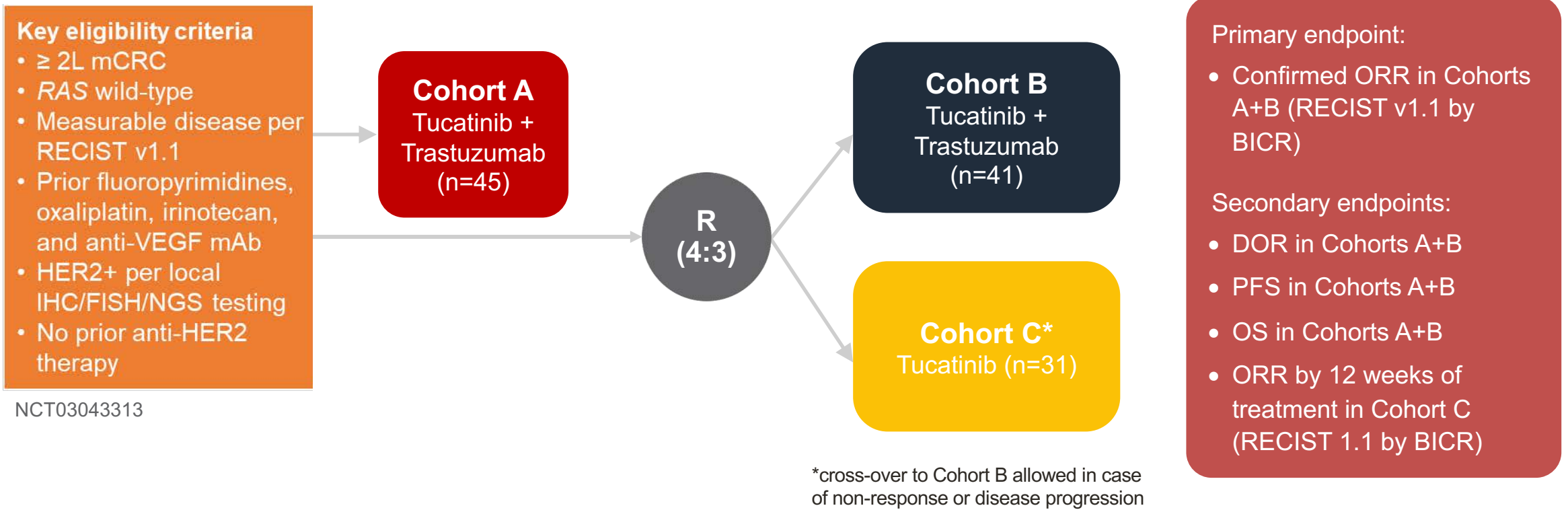
- IHC 3+
- IHC 2+ and ISH amplification
- In  $\geq 50\%$  tumor cells



CRC, colorectal cancer; HER2+, HER2 gene amplification; IHC, immunohistochemical stain; ISH, in situ hybridization; m, metastatic.  
1. Valtorta et al., Modern Pathology 2015.

Courtesy of John Strickler, MD

# MOUNTAINEER: Tucatinib + Trastuzumab for HER2+ mCRC - Phase 2 Study Design



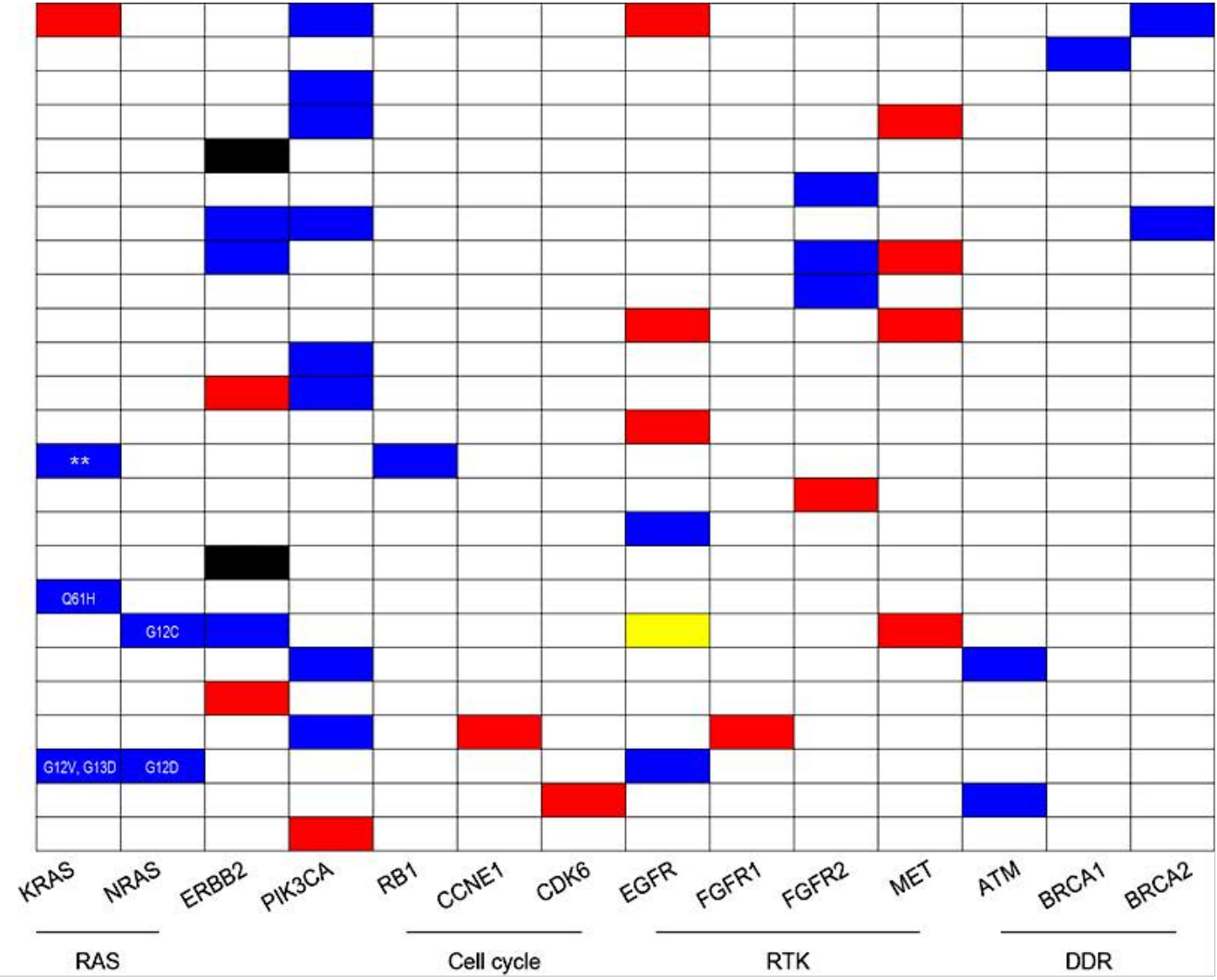
- Tucatinib is an oral, small molecule TKI that targets HER2
- Highly selective for the HER2 receptor
- Selectivity may improve tolerability (skin rash, diarrhea, etc.) compared to non-selective TKIs

Strickler JH et al. *Lancet Oncol.* 2023;24(5):496-508. Corti C et al. *ESMO Open.* 2021;6(2):100063. Moulder SL et al. *Clin Cancer Res.* 2017;23(14):3529-3536.



# MOUNTAINEER: Genomic Landscape of Acquired Alterations at Progression Timepoint or EOT

PR	16.5
PR	15.2
PR	13.1
PR	12.6
PR	12.5
PR	10.3
PR	8.3
PR	8.3
SD	8.1
PR	8.1
PR	8
PR	6.8
SD	4.4
SD	3.1
SD	2.8
SD	2.7
SD	2.7
SD	2.6
SD	2.6
SD	2.6
SD	2.1
PD	2.1
PD	1.7
PD	1.5
PD	1.1



n=31; 1 patient removed from analysis due to no detected alterations at baseline, leading to analysis set of 30; 23/30 showed alteration gains; 2/30 showed ERBB2 loss; 5/30 showed no alteration gains and no ERBB2 loss.

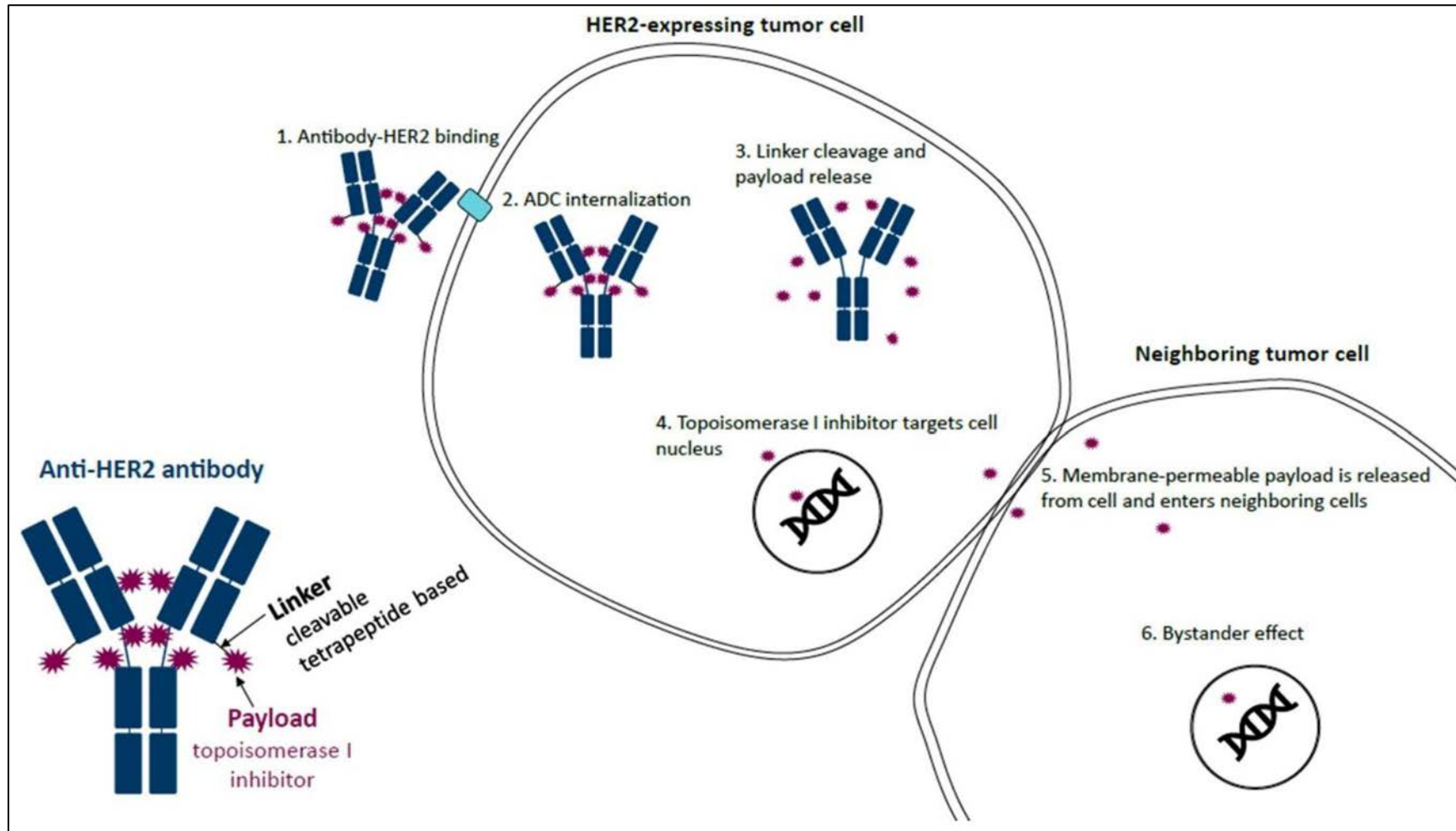
Blue box	SNV/INDEL
Red box	Amplification
Yellow box	SNV/INDEL and amplification
Black box	Loss of amplification

Note: a single BLUE or YELLOW box can represent multiple SNV/INDEL detections in the same gene

Response PFS  
 \*\*KRAS G13C, G12C, I24N

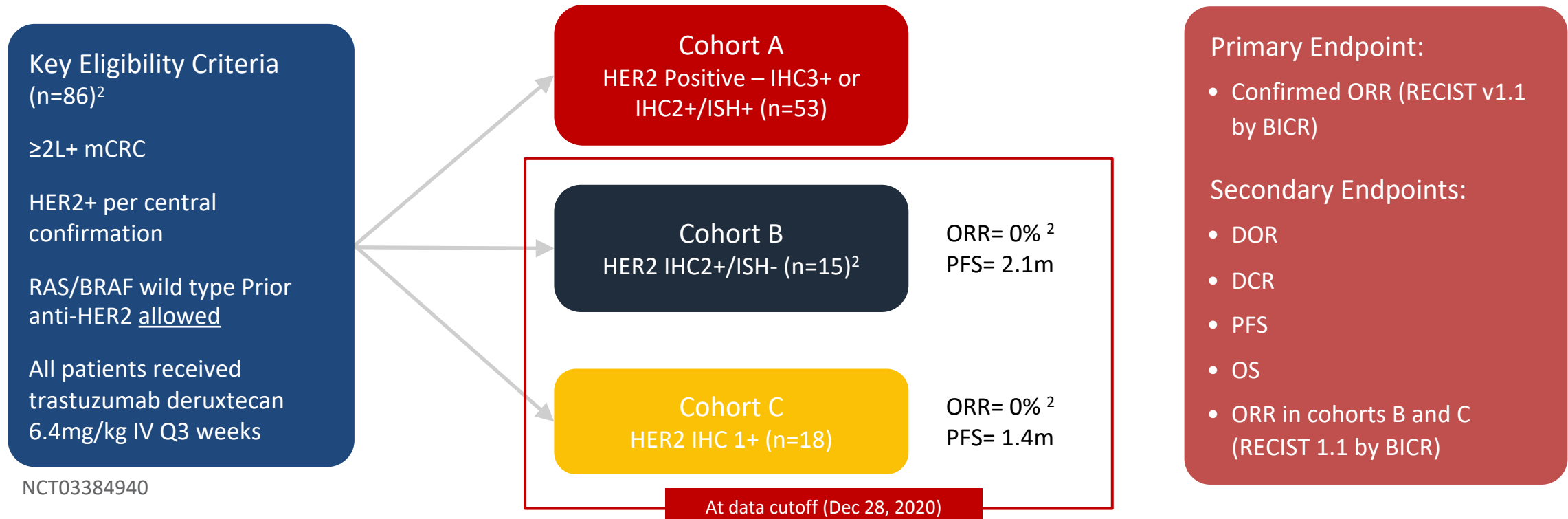
DDR: DNA Damage Response; EOT, end of treatment; PFS, progression-free survival; RTK: Receptor Tyrosine Kinase; SNV, single nucleotide variation

# Mechanism of action of trastuzumab deruxtecan (T-DXd)



Swain et al . Cancer Treatment Reviews. 106. May 2022

# DESTINY-CRC01: Trastuzumab deruxtecan (T-DXd; ds8201a) for HER2+ mCRC - Phase 2 Study Design



- T-DXd is an antibody drug conjugate with a humanized anti-HER2 IgG1 mAb similar to trastuzumab<sup>1</sup>
- Topoisomerase I inhibitor payload<sup>1</sup>
- High payload-to-antibody ratio (8:1)<sup>3</sup>

BICR = blinded independent central review; DCR = disease control rate; DOR = duration of response; HER2+ = HER2 gene amplification; IHC = immunohistochemistry; ISH = in situ hybridization; IV = intravenous; mAb = monoclonal antibody; mCRC = metastatic colorectal cancer; ORR, objective response rate; OS = overall survival; PFS = progression-free survival; Q3 = every 3 weeks; RECIST v1.1 = Response Evaluation Criteria in Solid Tumors

Courtesy of John Strickler, MD

# DESTINY-CRC01: Trastuzumab deruxtecan for HER2+ mCRC - Efficacy Outcomes

Cohort A, N=53 (response assessed by BICR)<sup>1-3</sup>

<b>Confirmed ORR, % (95% CI)</b>	45.3% (31.6-59.6)
<b>mDOR, months (95% CI)<sup>2</sup></b>	7.0 months (5.8-9.5)
<b>Disease control rate, % (95% CI)</b>	83.0% (70.2-91.9)
<b>PFS, months (95% CI)<sup>2</sup></b>	6.9 months (4.1-8.7)
<b>OS, months (95% CI)<sup>2</sup></b>	15.5 months (8.8-20.8)

Data cutoff (Dec 28, 2020)

BICR = blinded independent central review; CI = confidence interval; HER2+ = HER2 gene amplification;  
mCRC = metastatic colorectal cancer; NE = not evaluable; ORR = objective response rate; OS = overall survival;  
PFS = progression-free survival

Courtesy of John Strickler, MD

Siena S et al. *Lancet Oncol.* 2021;22(6):779-789. Yoshino T et al. 2021 ASCO Annual Meeting. Abstract 3505.

Yoshino T et al. *Nat Commun.* 2023;14(1):3332.

# DESTINY-CRC01: Trastuzumab deruxtecan for HER2+ mCRC - Subgroup analyses

Cohort A, N=53 (response assessed by BICR)

	N	ORR (%)	95% CI
<b>Cohort A overall</b>	53	45.3	31.6-59.6
<b>HER2 status</b>			
IHC3+	40	57.5	40.9-73.0
IHC2+ and ISH-positive	13	7.7	0.2-36.0
<b>Previous HER2 treatment</b>			
Yes	16	43.8	19.8-70.1
No	37	45.9	29.5-63.1

BICR = blinded independent central review; CI = confidence interval; HER2+ = HER2 gene amplification; mCRC = metastatic colorectal cancer; NE = not evaluable; ORR = objective response rate; OS = overall survival; PFS = progression-free survival

# DESTINY-CRC02: Trastuzumab deruxtecan for HER2+ mCRC - Efficacy Outcomes

	5.4 mg/kg Q3W (n = 82)	6.4 mg/kg Q3W (n = 40)
Confirmed ORR, % (95% CI)	37.8% (27.3-49.2)	27.5% (14.6-43.9)
mDOR, months (95% CI)	5.5 months (4.2-8.1)	5.5 months (3.7-NE)
Disease control rate, % (95% CI)	86.6% (77.3-93.1)	85.0% (70.2-94.3)
PFS, months (95% CI)	5.8 months (4.6-7.0)	5.5 (4.2-7.0)
OS, months (95% CI)	13.4 months (12.5-16.8)	NE (9.9-NE)

Courtesy of John Strickler, MD







# Treatment of HER2+ metastatic colorectal cancer: Key takeaways

- All patients with metastatic CRC should be tested for HER2 overexpression/ amplification
- My testing practice:
  - Order tissue NGS at time of diagnosis of metastatic disease
  - If *ERBB2* amplification found on tissue NGS, then consider HER2 IHC
- T-DXd and tucatinib+trastuzumab are the only FDA-approved therapies for HER2+ metastatic CRC
  - Tucatinib + trastuzumab is an effective and generally well tolerated chemotherapy-free regimen (well suited to RAS WT, HER2-naïve pt)
  - T-DXd is also active in patients with HER2 IHC= 3+, including *RAS* mutated tumors
  - T-DXd is active after progression on prior anti-HER2 therapies







Courtesy of John Strickler, MD









Regulatory and reimbursement issues aside, what would be your likely second-line treatment for a patient with right-side pan-RAS wild-type, BRAF wild-type, MSS, HER2-positive mCRC as described below who received FOLFOX/bevacizumab and experienced disease progression after 9 months of maintenance bevacizumab?

	IHC 3+	IHC 2+, FISH-positive
 Dr Bekaii-Saab	Trastuzumab/tucatinib	Trastuzumab/tucatinib
 Dr Strickler	Trastuzumab/tucatinib	FOLFIRI/CAPIRI + bevacizumab
 Dr Ciombor	Trastuzumab/tucatinib	Trastuzumab/tucatinib
 Dr Lieu	Trastuzumab/tucatinib	Trastuzumab/tucatinib
 Dr Mehta	Trastuzumab/tucatinib, T-DXd, or add back FOLFOX	Trastuzumab/tucatinib, T-DXd, or add back FOLFOX
 Dr Philip	Trastuzumab/tucatinib	Trastuzumab/tucatinib







Regulatory and reimbursement issues aside, what would be your likely second-line treatment for a patient with right-side pan-RAS wild-type, BRAF wild-type, MSS, HER2-positive mCRC as described below who received FOLFOX/bevacizumab and experienced disease progression after 9 months of maintenance bevacizumab?

	IHC 2+, FISH-negative	With a HER2 mutation
 <b>Dr Bekaii-Saab</b>	Trastuzumab deruxtecan	FOLFIRI/CAPIRI + bevacizumab
 <b>Dr Strickler</b>	FOLFIRI/CAPIRI + bevacizumab	FOLFIRI/CAPIRI + bevacizumab
 <b>Dr Ciombor</b>	FOLFIRI/CAPIRI + bevacizumab	FOLFIRI/CAPIRI + bevacizumab
 <b>Dr Lieu</b>	FOLFIRI + bevacizumab	FOLFIRI + bevacizumab
 <b>Dr Mehta</b>	FOLFIRI/CAPIRI ± bevacizumab, FOLFOXIRI ± bevacizumab, or add back FOLFOX	FOLFIRI/CAPIRI ± bevacizumab, FOLFOXIRI ± bevacizumab, or add back FOLFOX
 <b>Dr Philip</b>	FOLFIRI/CAPIRI + bevacizumab	Trastuzumab/tucatinib

Regulatory and reimbursement issues aside, what would be your likely second-line treatment for a patient with left-side pan-RAS wild-type, BRAF wild-type, MSS, HER2-positive mCRC as described below who received FOLFOX/bevacizumab and experienced disease progression after 9 months of maintenance bevacizumab?

	IHC 3+	IHC 2+, FISH-positive
 Dr Bekaii-Saab	Trastuzumab/tucatinib	Trastuzumab/tucatinib
 Dr Strickler	Trastuzumab/tucatinib	Trastuzumab/tucatinib
 Dr Ciombor	Trastuzumab/tucatinib	Trastuzumab/tucatinib
 Dr Lieu	Trastuzumab/tucatinib	Trastuzumab/tucatinib
 Dr Mehta	Trastuzumab/tucatinib, T-DXd, or add back FOLFOX	Trastuzumab/tucatinib, T-DXd, or add back FOLFOX
 Dr Philip	Trastuzumab/tucatinib	Trastuzumab/tucatinib

Regulatory and reimbursement issues aside, what would be your likely second-line treatment for a patient with left-side pan-RAS wild-type, BRAF wild-type, MSS, HER2-positive mCRC as described below who received FOLFOX/bevacizumab and experienced disease progression after 9 months of maintenance bevacizumab?

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 Dr Strickler	FOLFIRI/CAPIRI + bevacizumab	FOLFIRI/CAPIRI + bevacizumab
 Dr Ciombor	FOLFIRI/CAPIRI + bevacizumab	FOLFIRI/CAPIRI + bevacizumab
 Dr Lieu	FOLFIRI + EGFR antibody	FOLFIRI + EGFR antibody
 Dr Mehta	FOLFIRI/CAPIRI ± bevacizumab, FOLFOXIRI ± bevacizumab, or add back FOLFOX	FOLFIRI/CAPIRI ± bevacizumab, FOLFOXIRI ± bevacizumab, or add back FOLFOX
 Dr Philip	FOLFIRI/CAPIRI + bevacizumab	Trastuzumab/tucatinib

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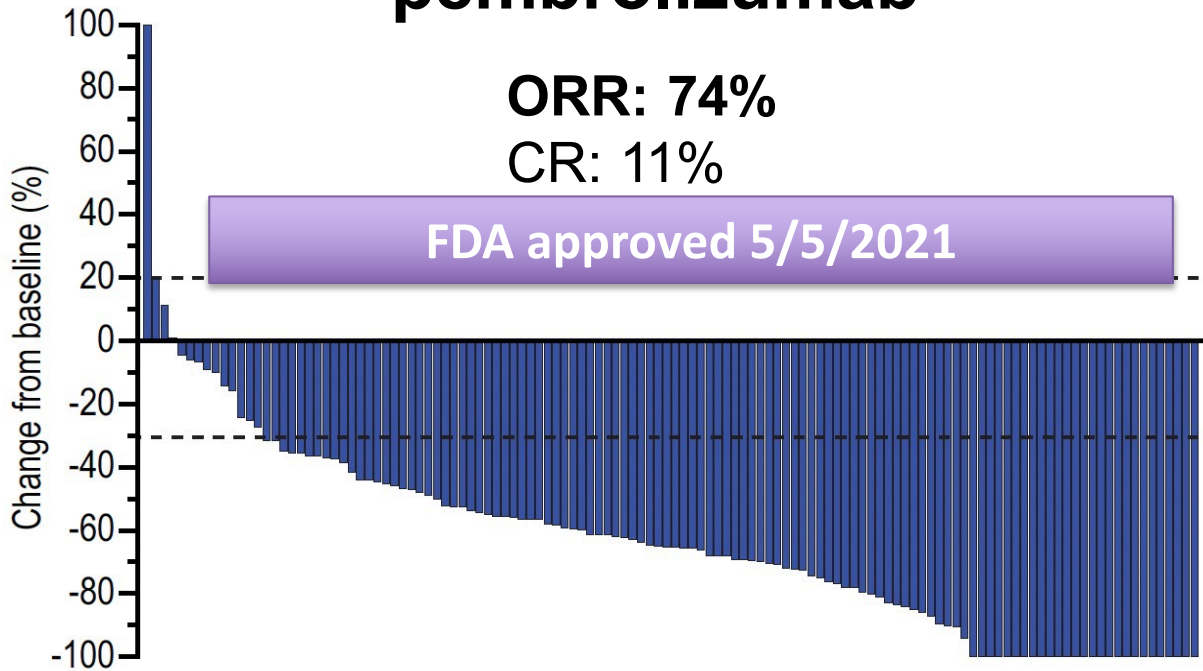
– Biliary Tract Cancer

**Module 3: Toxicities Associated with Anti-HER2 Treatment**

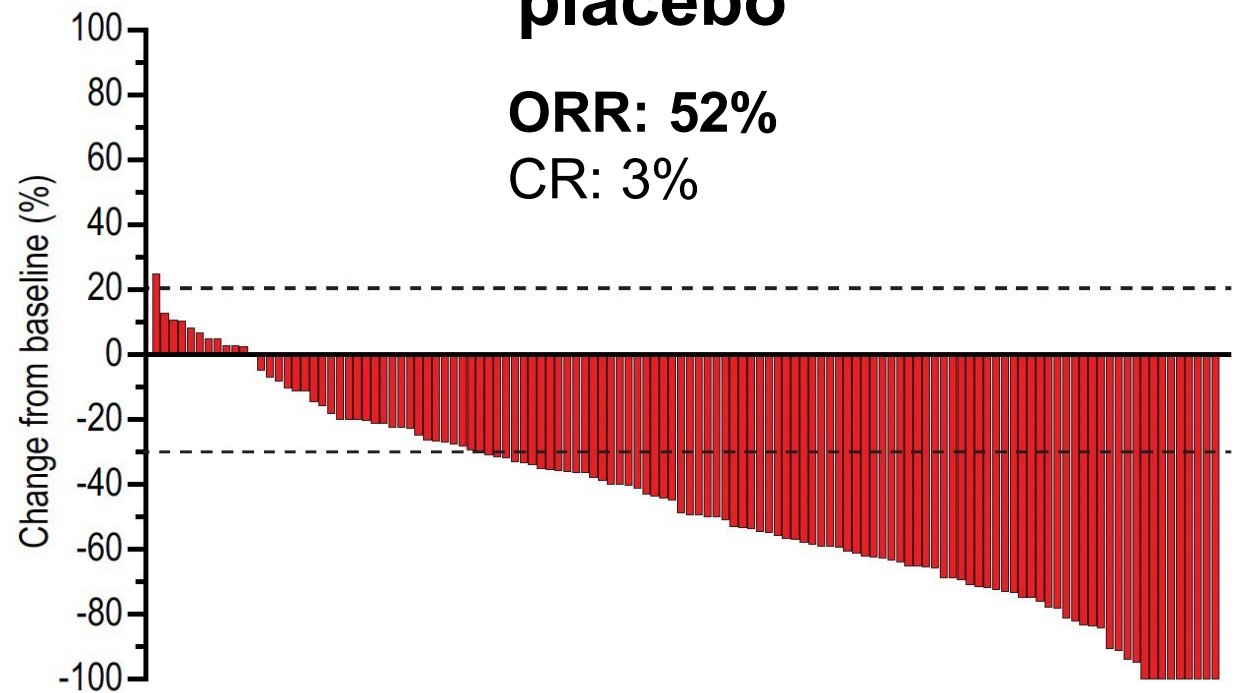
**Module 4: Novel Agents and Strategies for HER2-Positive GI Cancers**

# KEYNOTE-811: Overall response rate favors pembrolizumab\*

## Chemo + trastuzumab + pembrolizumab



## Chemo + trastuzumab + placebo



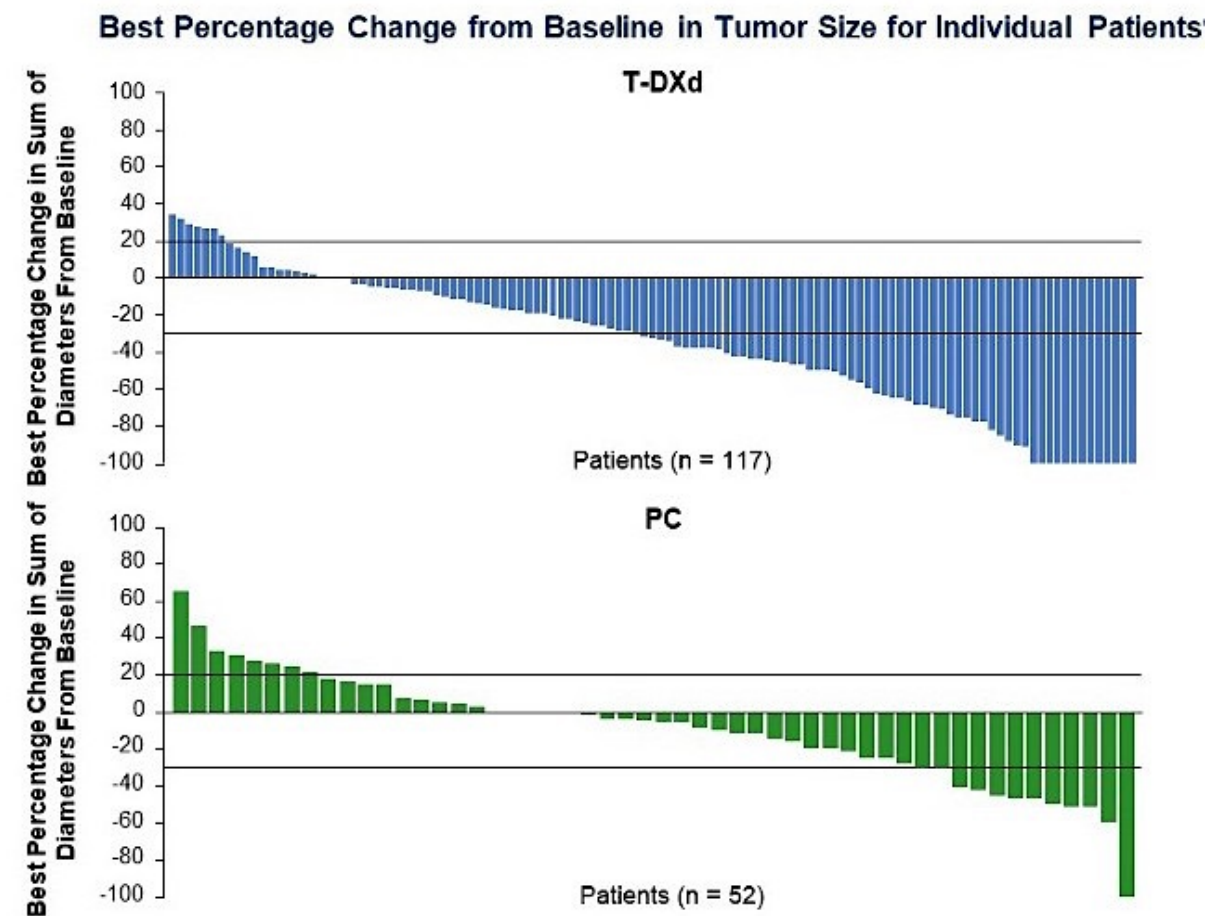
\* Interim analysis #1

Courtesy of John Strickler, MD



# DESTINY-Gastric01: T-DXd superior to SOC

	T-DXd n = 119	PC Overall n = 56
<b>ORR (CR + PR) by ICR, n (%)<sup>a</sup></b>	<b>61 (51.3)</b> 95% CI, 41.9-60.5	<b>8 (14.3)</b> 95% CI, 6.4-26.2
	<i>P</i> < 0.0001 <sup>b</sup>	
CR	11 (9.2)	0
PR	50 (42.0)	8 (14.3)
SD	42 (35.3)	27 (48.2)
PD	14 (11.8)	17 (30.4)
Not evaluable	2 (1.7)	4 (7.1)
<b>Confirmed ORR (CR + PR) by ICR, n (%)<sup>a</sup></b>	<b>50 (42.0)</b> 95% CI, 33.0-51.4	<b>7 (12.5)</b> 95% CI, 5.2-24.1
CR	10 (8.4)	0
PR	40 <sup>c</sup> (33.6)	7 (12.5)
SD	52 (43.7)	28 (50.0)
PD	14 (11.8)	17 (30.4)
Not evaluable	3 (2.5)	4 (7.1)
<b>Confirmed DCR (CR + PR + SD), n (%)<sup>a</sup></b>	<b>102 (85.7)</b> 95% CI, 78.1-91.5	<b>35 (62.5)</b> 95% CI, 48.5-75.1
<b>Confirmed DOR, median, months</b>	<b>12.5</b> 95% CI, 5.6-NE	<b>3.9</b> 95% CI, 3.0-4.9
<b>TTR, median, months</b>	<b>1.5</b> 95% CI, 1.4-1.7	<b>1.6</b> 95% CI, 1.3-1.7



Courtesy of John Strickler, MD

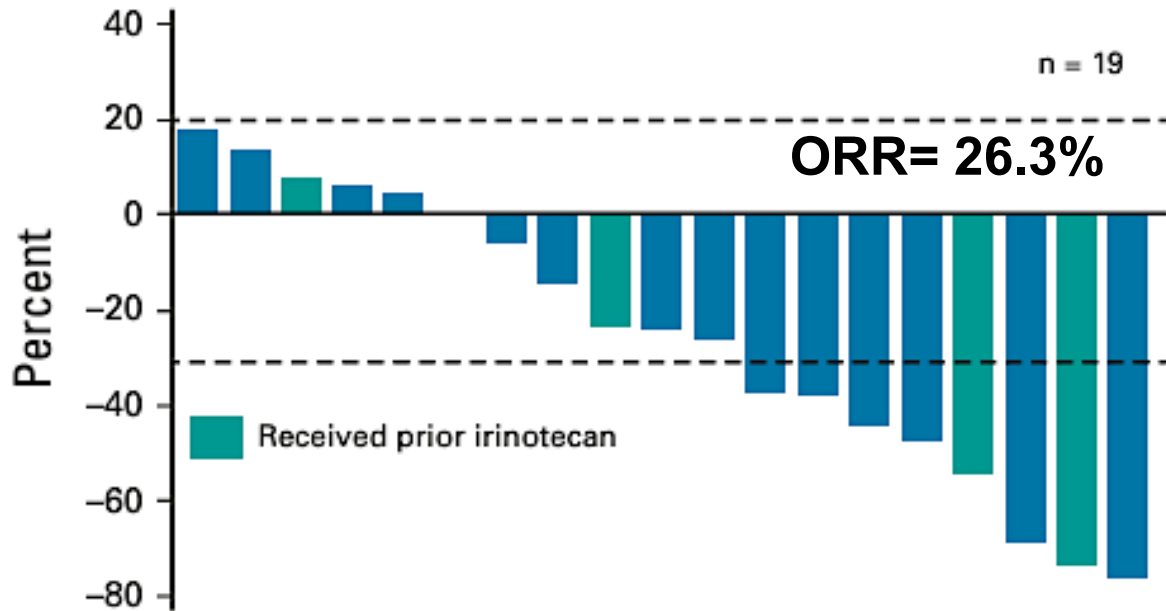
Yamaguchi K et al. ASCO Gastrointestinal Cancers Symposium 2022; Abstract 242.

Shitara et al. *N Engl J Med* 2020;382:2419-2430.

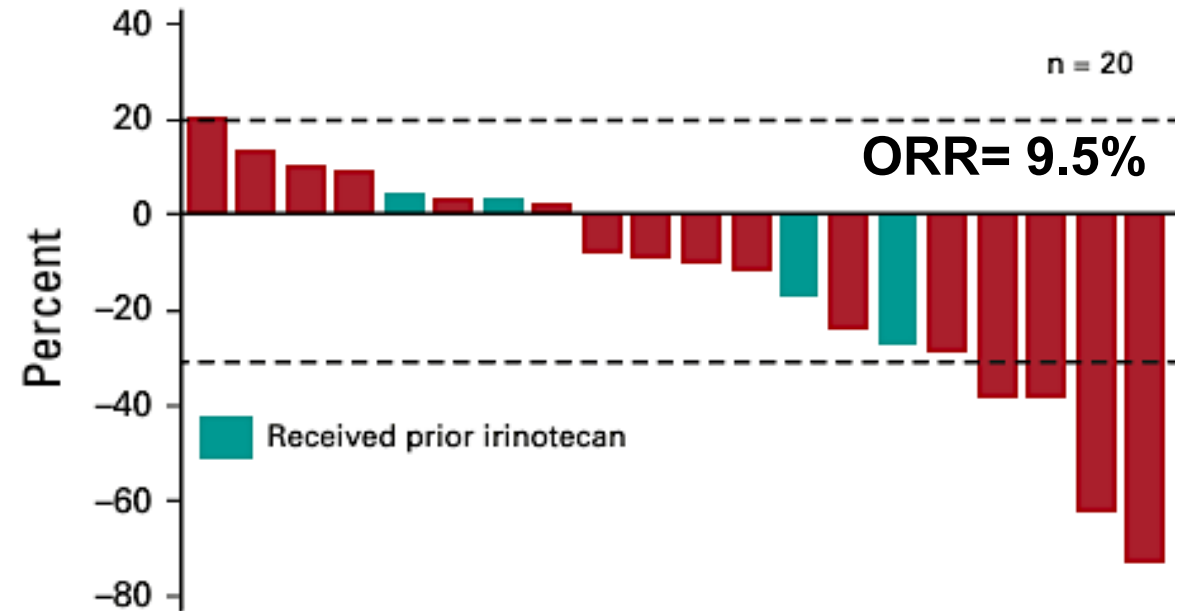


# DESTINY-Gastric01: T-DXd activity for HER2 intermediate/ low expressing tumors

**Cohort 1  
(HER2 IHC2+/ ISH-)**



**Cohort 2  
(HER2 IHC1+)**



Courtesy of John Strickler, MD

# DESTINY-Gastric02: T-DXd in US/European patients with HER2+ gastric/ gastroesophageal cancer ( $\geq 2L$ )

Response Assessment by ICR	April 9, 2021 Data Cutoff <sup>a</sup> Patients (N = 79)	November 8, 2021 Data Cutoff <sup>b</sup> Patients (N = 79)
<b>Confirmed ORR,<sup>c</sup> % (n)</b>	<b>38.0</b> (30) (95% CI, 27.3-49.6)	<b>41.8</b> (33) (95% CI, 30.8-53.4)
<b>Confirmed best overall response, % (n)</b>		
CR	<b>3.8</b> (3)	<b>5.1</b> (4)
PR	<b>34.2</b> (27)	<b>36.7</b> (29)
SD	<b>43.0</b> (34)	<b>39.2</b> (31)
PD	<b>16.5</b> (13)	<b>16.5</b> (13)
Not evaluable	<b>2.5</b> (2)	<b>2.5</b> (2)
<b>Confirmed DCR,<sup>d</sup> % (n)</b>	<b>81.0</b> (64) (95% CI, 70.6-89.0)	<b>81.0</b> (64) (95% CI, 70.6-89.0)
<b>Median DoR, months</b>	8.1 (95% CI, 4.1-NE)	8.1 (95% CI, 5.9-NE) <sup>e</sup>
<b>Median TTR, months</b>	1.4 (95% CI, 1.4-2.6)	1.4 (95% CI, 1.4-2.7)

Median OS at November 8, 2021 data cutoff = 12.1 mo; median PFS = 5.6 mo

AE rates similar to DESTINY-Gastric01; Grade 1-2 pneumonitis= 9%; Grade 5 pneumonitis = 1%

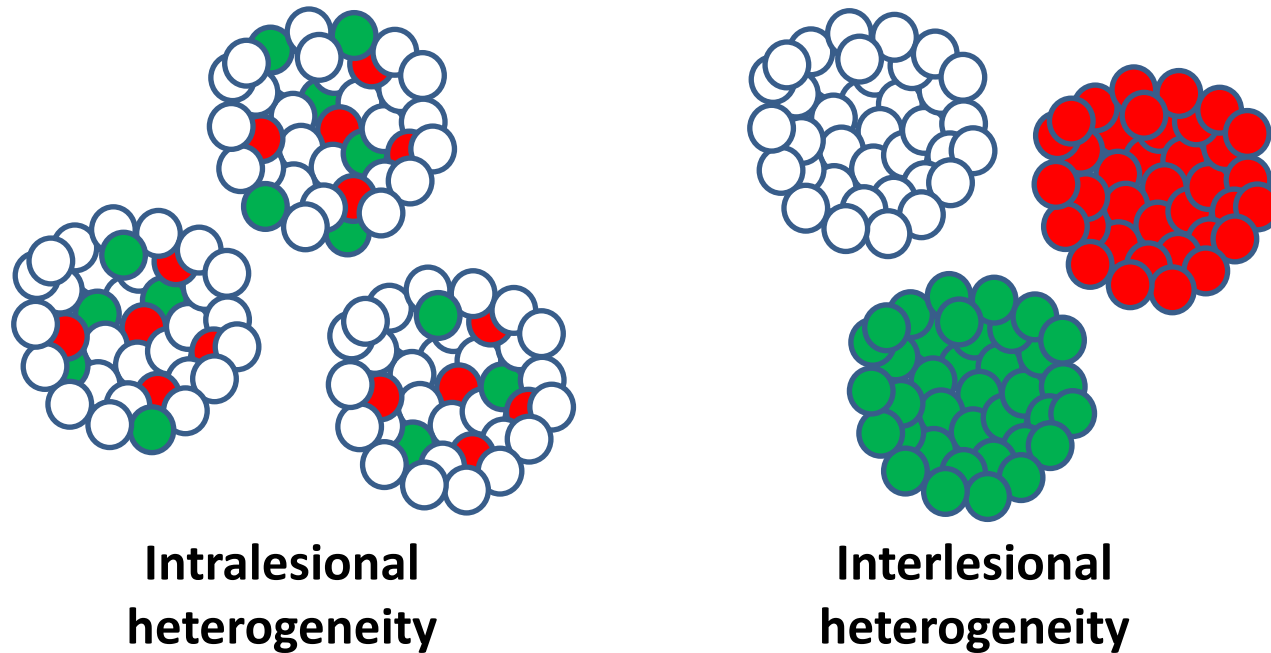
Courtesy of John Strickler, MD

Ku et al. Presented at ESMO Congress 2022; Presentation 1205MO.

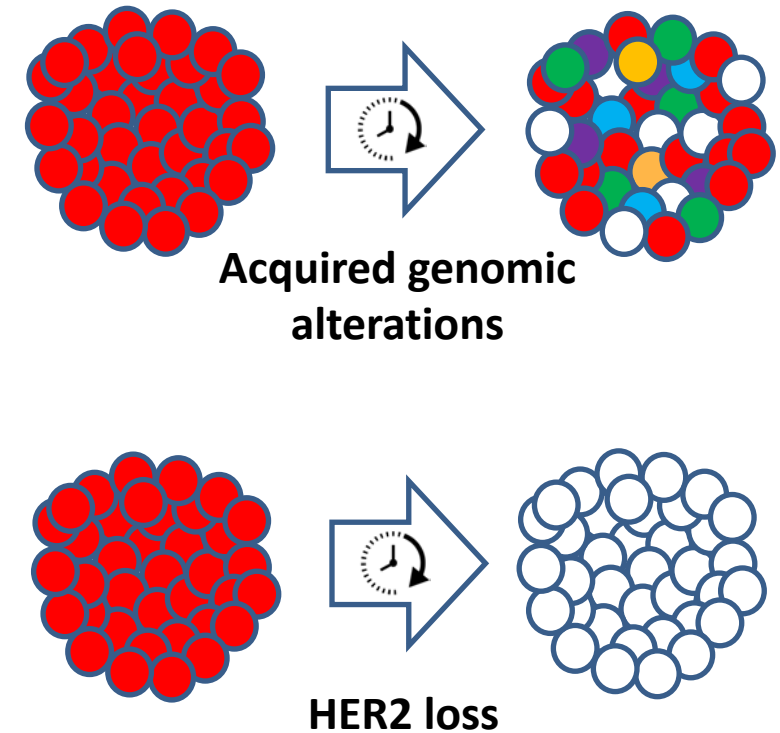
Van Cutsem et al. *Lancet Oncol* 2023;24:744-56.

# Heterogeneity drives resistance to HER2 therapies in patients with HER2+ metastatic gastroesophageal cancer

## Spatial heterogeneity



## Temporal heterogeneity









HER2 loss and/or gain of *KRAS/PIK3CA* mutations observed in ~30% of post-progression samples

# Treatment of HER2+ metastatic gastroesophageal cancer: Key takeaways







- All patients should be tested for HER2 at the time of diagnosis of metastatic disease
- Consider sequential testing of HER2, PD-L1, MSI/MMR, tumor agnostic biomarkers (via NGS)
- Preferred 1L option: FOLFOX + trastuzumab + pembrolizumab (if PD-L1+)
- Consider retesting HER2 after progression on 1L therapy
- T-DXd is active (and FDA-approved) for pts with IHC3+ or IHC2+/ISH-positive disease who have received a prior trastuzumab-based regimen

Courtesy of John Strickler, MD

Regulatory and reimbursement issues aside, what would be your preferred first-line anti-HER2 treatment for a patient with newly diagnosed metastatic HER2-positive (IHC 3+), MSS gastroesophageal adenocarcinoma with a PD-L1 combined positive score (CPS) of 0, and what other options would you consider?

	Initial anti-HER2 treatment	Other options
 Dr Bekaii-Saab	Trastuzumab/chemotherapy	None
 Dr Strickler	Trastuzumab/FOLFOX	Trastuzumab/CAPOX
 Dr Ciombor	Trastuzumab/FOLFOX	Trastuzumab/CAPOX or 5-FU/cisplatin/trastuzumab
 Dr Lieu	Trastuzumab/FOLFOX/ pembrolizumab	Trastuzumab/FOLFOX
 Dr Mehta	FOLFOX	Zanidatamab/chemotherapy
 Dr Philip	Trastuzumab/FOLFOX or CAPOX	None

Regulatory and reimbursement issues aside, what would you currently recommend as second-line therapy for a patient with metastatic HER2-positive (IHC 3+), MSS gastroesophageal adenocarcinoma with a PD-L1 CPS of 0 who experienced disease progression on FOLFOX/trastuzumab, and what other options would you consider?

	Second-line treatment	Other options
 Dr Bekaii-Saab	Trastuzumab deruxtecan	None
 Dr Strickler	Trastuzumab deruxtecan	Ramucirumab/paclitaxel, ramucirumab, FOLFIRI +/- ramucirumab
 Dr Ciombor	Trastuzumab deruxtecan	Tucatinib/trastuzumab +/- ramucirumab/paclitaxel
 Dr Lieu	Trastuzumab deruxtecan	Ramucirumab/paclitaxel
 Dr Mehta	Trastuzumab deruxtecan	Tucatinib/trastuzumab
 Dr Philip	Trastuzumab deruxtecan	Tucatinib/trastuzumab

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**Introduction: Back to School Special**

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**Module 2: Sequencing of Treatment for HER2-Positive GI Cancers**

- Colorectal Cancer
- Gastroesophageal Cancer
- Biliary Tract Cancer

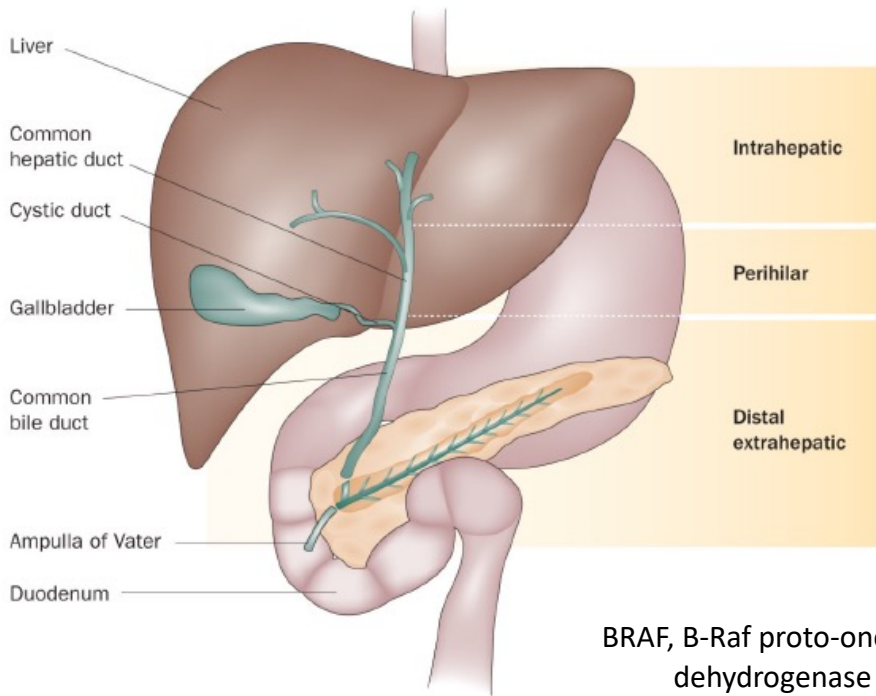
**Module 3: Toxicities Associated with Anti-HER2 Treatment**

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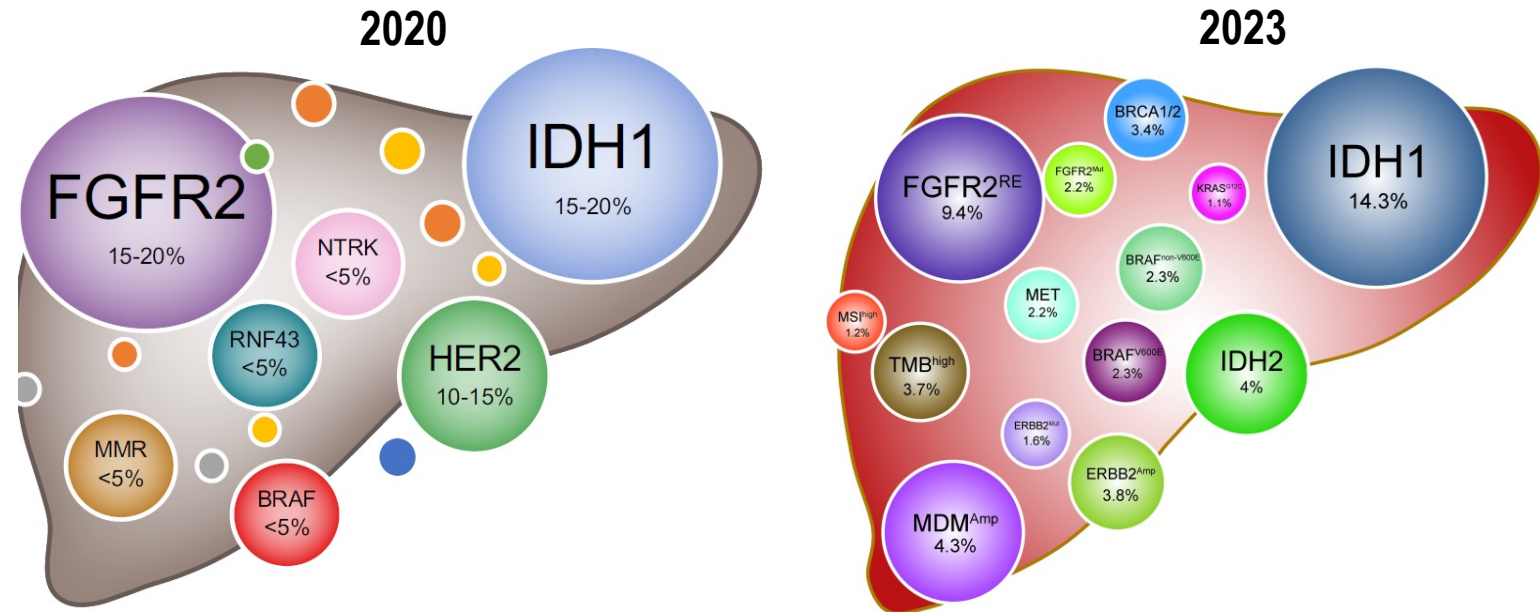


# From anatomical to molecular subgroups

## Anatomical<sup>1</sup>



## Molecular<sup>2,3</sup>

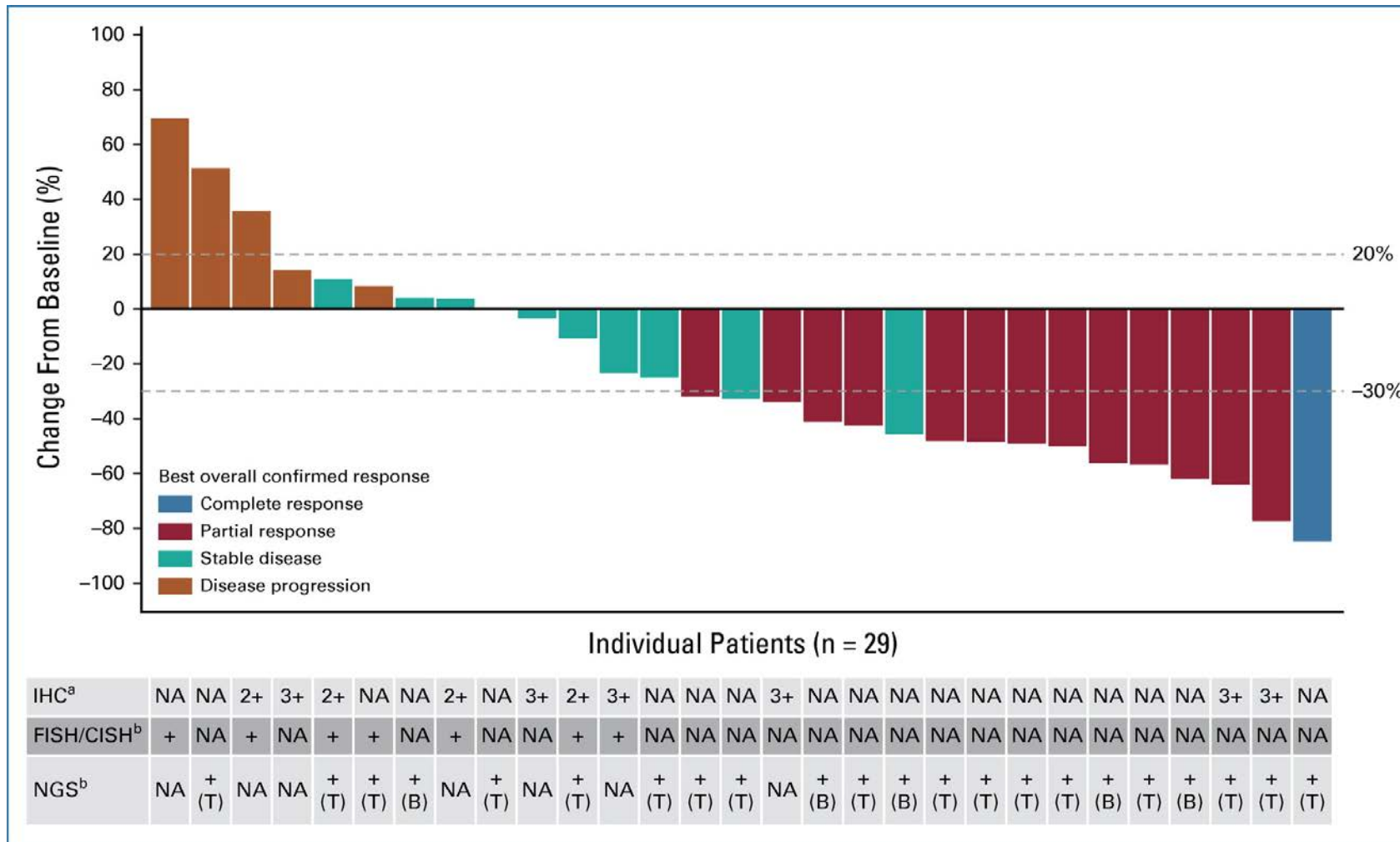


BRAF, B-Raf proto-oncogene; FGFR2, fibroblast growth factor receptor 2; HER2, human epidermal growth factor receptor 2; IDH1, isocitrate dehydrogenase 1; MMR, mismatch repair deficiency; NTRK, neurotrophic receptor tyrosine kinase; RNF43, ring finger protein 43.

1. Blechacz et al *Nat Rev Gastroenterol Hepatol* 2011;8:512–22
2. Lamarca et al *J Hepatol* 2020 Jul;73(1):170-185
3. Kendre et al. *J Hepatol* 2023 Mar;78(3):614-626

# Tucatinib and Trastuzumab for Previously Treated Human Epidermal Growth Factor Receptor 2–Positive Metastatic Biliary Tract Cancer (SGNTUC-019)

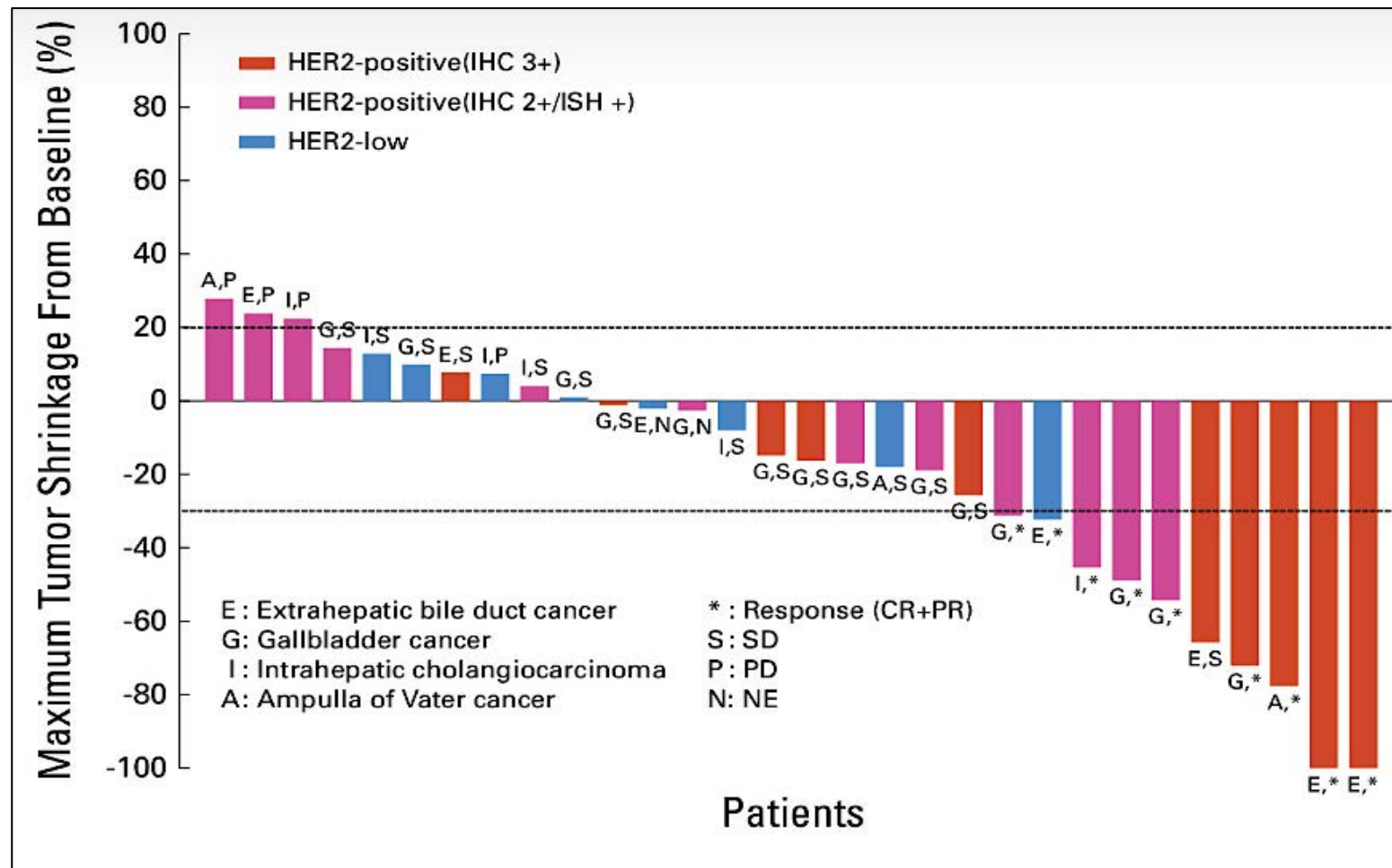
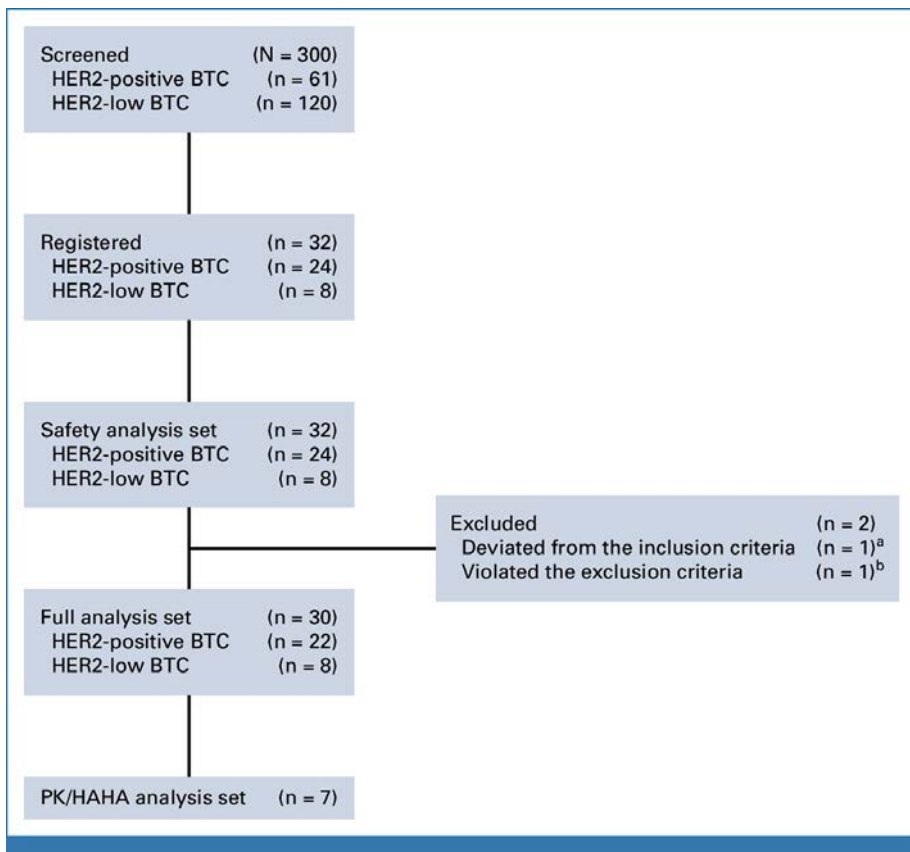
Nakamura and Bekaii-Saab et al . J Clin Oncol 2023



Courtesy of Tanios Bekaii-Saab, MD

# Trastuzumab Deruxtecan in Human Epidermal Growth Factor Receptor 2–Expressing Biliary Tract Cancer (HERB; NCCH1805): A Multicenter, Single-Arm, Phase II Trial

Ohba et al. J Clin Oncol 2024









Courtesy of Tanios Bekaii-Saab, MD

# Biliary Tract Cancer Conclusions/Take-Aways







- NGS ( + emerging liquid platforms) testing is central to future applications of novel therapies in Biliary Cancer
  - Applying genomic technology and molecular classification critically and timely in cholangiocarcinoma is changing the therapeutic landscape.
- Molecularly targeted agents such as those targeting HER2 are providing patients with advanced cholangiocarcinoma new treatment options
  - Drug resistance mechanisms and novel strategies to overcome drug resistance

Regulatory and reimbursement issues aside, what would be your most likely initial anti-HER2 treatment for a patient with advanced HER2-overexpressing (IHC 3+) biliary tract cancer (PS 0), and what other options would you consider?

	Initial anti-HER2 treatment	Other options
 Dr Bekaii-Saab	Tucatinib/trastuzumab	None
 Dr Strickler	Trastuzumab deruxtecan	Tucatinib/trastuzumab, trastuzumab/pertuzumab, zanidatamab
 Dr Ciombor	Tucatinib/trastuzumab	Trastuzumab/pertuzumab, T-DXd, zanidatamab
 Dr Lieu	Trastuzumab deruxtecan	Zanidatamab
 Dr Mehta	I would not recommend anti-HER2 treatment in this setting	None
 Dr Philip	Tucatinib/trastuzumab	Zanidatamab



Regulatory and reimbursement issues aside, what would be your preferred second-line systemic treatment for a patient with advanced HER2-overexpressing (IHC 3+) biliary tract cancer (PS 0) who experienced disease progression after durvalumab/cisplatin/gemcitabine, and what other options would you consider?

	Second-line treatment	Other options
 <b>Dr Bekaii-Saab</b>	Tucatinib/trastuzumab	None
 <b>Dr Strickler</b>	Trastuzumab deruxtecan	Tucatinib/trastuzumab, zanidatamab, trastuzumab/pertuzumab
 <b>Dr Ciombor</b>	Tucatinib/trastuzumab	T-DXd, trastuzumab/pertuzumab, zanidatamab
 <b>Dr Lieu</b>	Trastuzumab deruxtecan	Zanidatamab
 <b>Dr Mehta</b>	Trastuzumab deruxtecan or tucatinib/trastuzumab	FOLFOX, FOLFIRI, regorafenib, zanidatamab, nivolumab, pembrolizumab/lenvatinib
 <b>Dr Philip</b>	Tucatinib/trastuzumab	Zanidatamab

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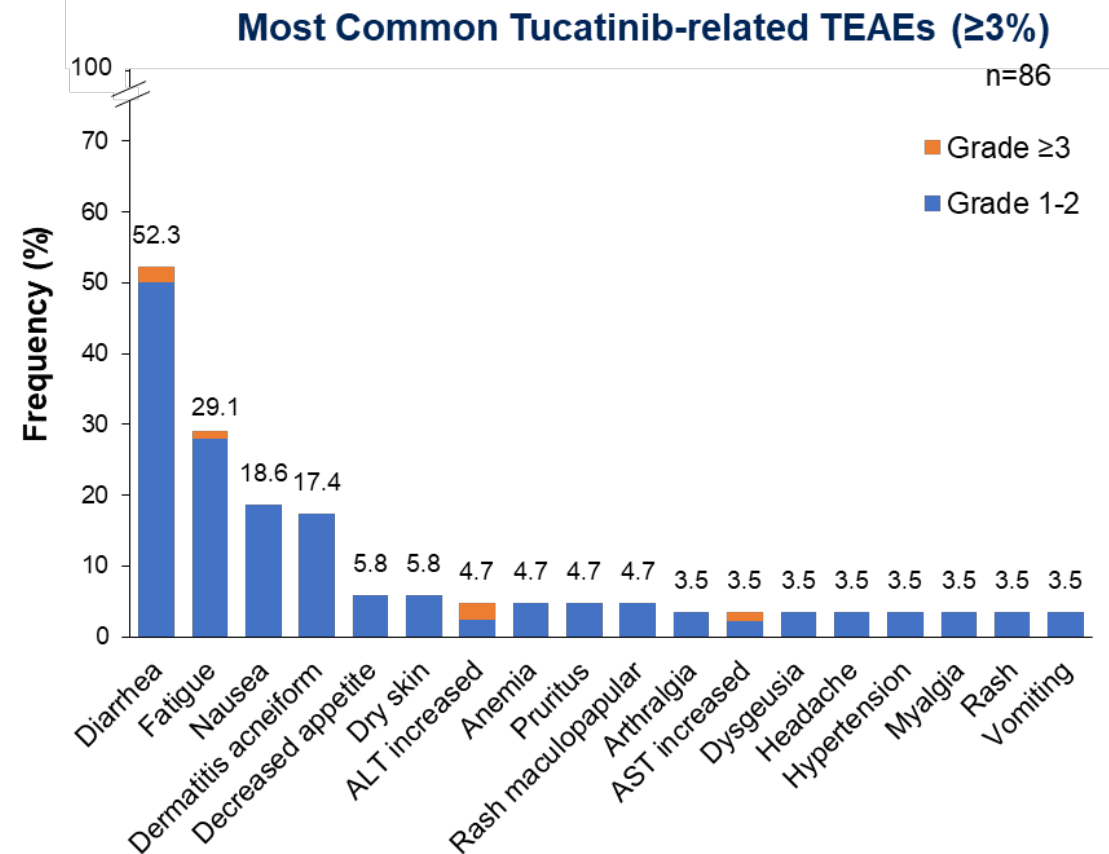
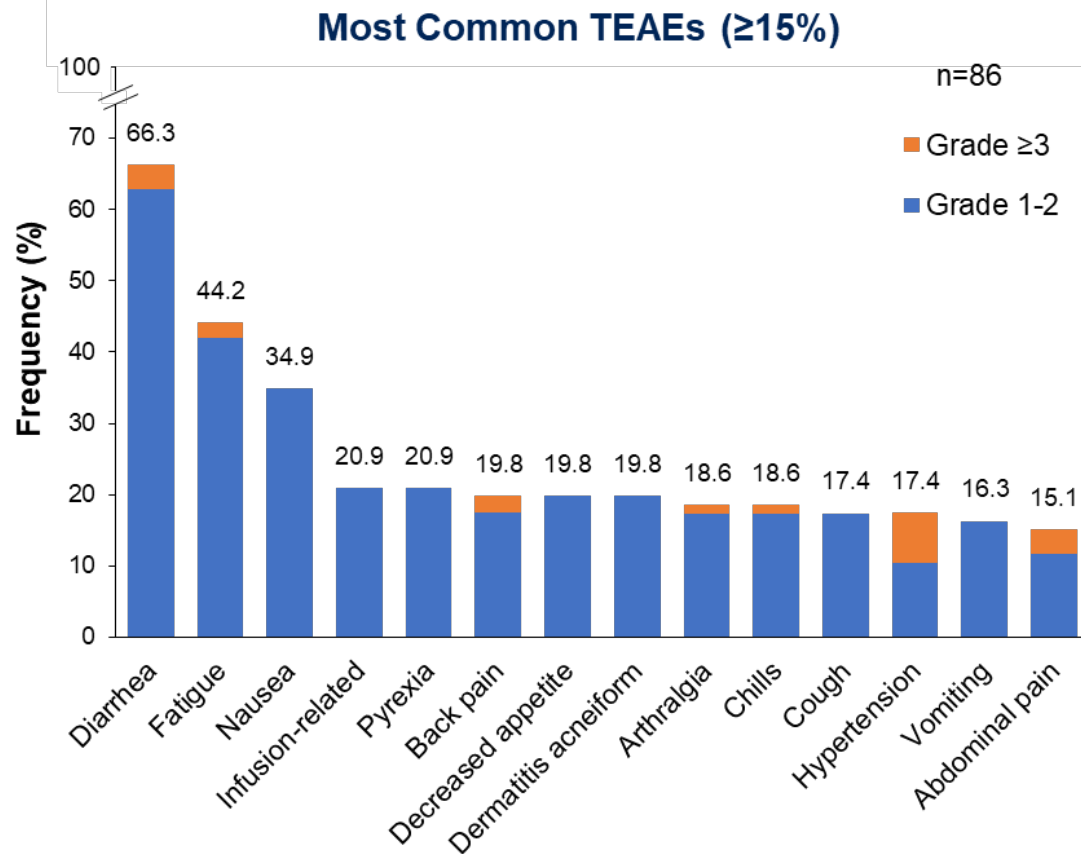
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# MOUNTAINEER: Tucatinib + trastuzumab AE profile

- Majority of TEAEs were low grade, and rates were stable with longer follow-up
- Common TEAEs included diarrhea (66.3%), fatigue (44.2%) and nausea (34.9%)
- Most tucatinib-related TEAEs were of low grade



AE, adverse event; ALT, alanine aminotransferase; AST, aspartate aminotransferase; TEAE, treatment-emergent adverse event.

Courtesy of John Strickler, MD

Strickler et al. Presented at 2024 ASCO Annual Meeting  
Strickler et al. *J Clin Oncol* 42, 2024 (suppl 16; abstr 3509).

# DESTINY-CRC02: Adjudicated Drug-Related ILD/ Pneumonitis by Independent Adjudication Committee

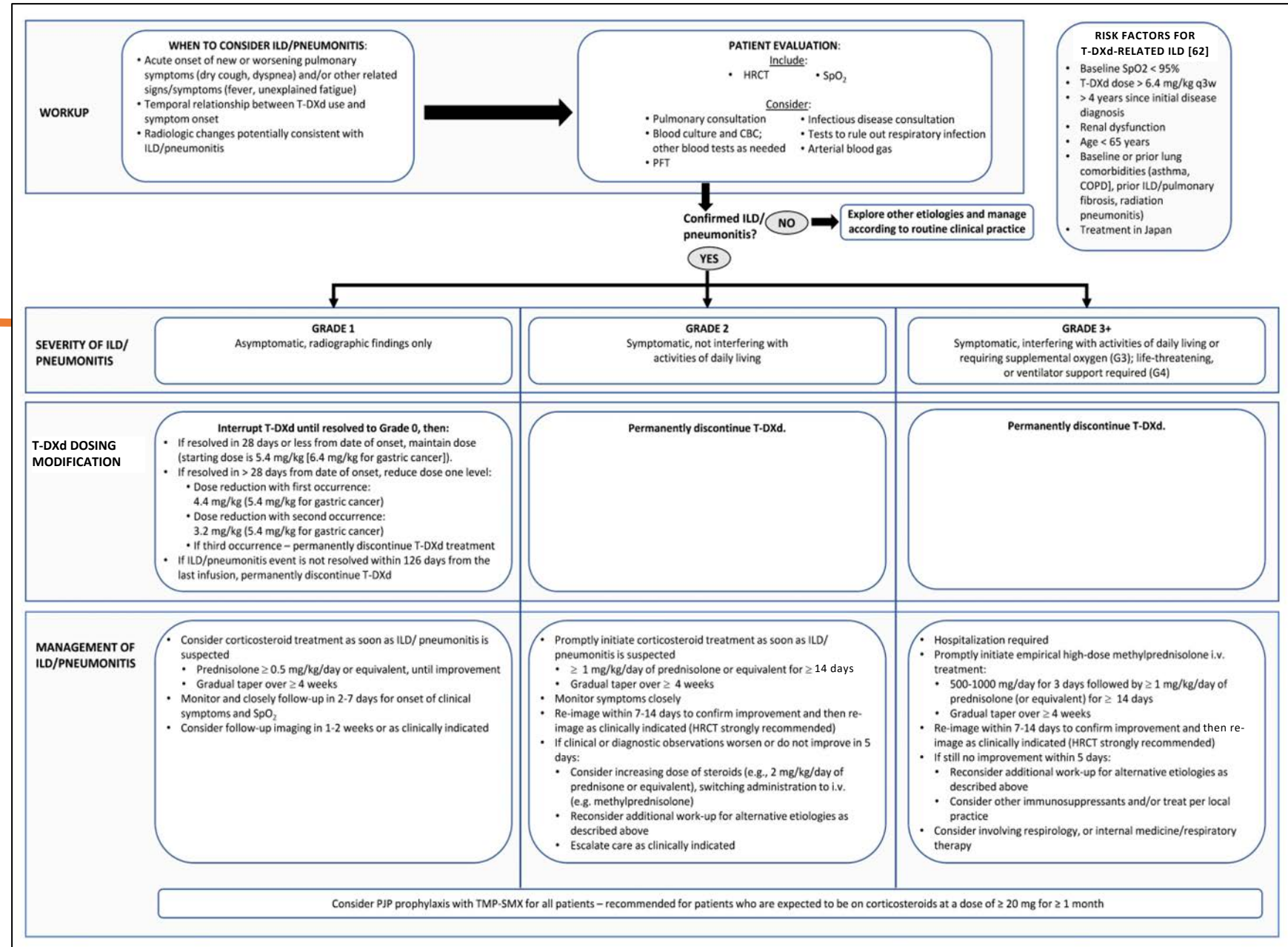
Adjudicated as drug-related ILD/pneumonitis, n (%)	T-DXd 5.4 mg/kg Q3W			T-DXd 6.4 mg/kg Q3W
	Stage 1 n = 41 <sup>a</sup>	Stage 2 n = 42	Total N = 83	Stage 1 N = 39
Any grade	4 (9.8)	3 (7.1)	7 (8.4)	5 (12.8)
Grade 1	1 (2.4)	0	1 (1.2)	2 (5.1)
Grade 2	3 (7.3)	3 (7.1)	6 (7.2)	2 (5.1)
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Grade 5	0	0	0	1 (2.6)

Courtesy of John Strickler, MD

Raghav K et al. 2023 ASCO Annual Meeting. Abstract 3501.  
Raghav et al. [Lancet Oncol](#) 2024 (published online).







# Management of interstitial lung disease/pneumonitis in patients undergoing treatment with trastuzumab deruxtecan (T-DXd)

Henning et al . Current Oncology 2023 . 30(9), 8019-8038;



Courtesy of Tanios Bekaii-Saab, MD

At what grade of ILD would you permanently discontinue therapy with trastuzumab deruxtecan for a patient with HER2-positive GI cancer?

	Colorectal cancer	Gastroesophageal cancer	Biliary tract cancers
 Dr Bekaii-Saab	Grade 2	Grade 2	Grade 2
 Dr Strickler	Grade 2	Grade 2	Grade 2
 Dr Ciombor	Grade 2	Grade 2	Grade 2
 Dr Lieu	Grade 2	Grade 2	Grade 2
 Dr Mehta	Grade 2	Grade 2	Grade 2
 Dr Philip	Grade 1	Grade 2	Grade 2

Based on available data and your personal clinical experience, how would you characterize the degree of alopecia observed with trastuzumab deruxtecan in patients with GI cancers?



**Dr Bekaii-Saab**

**Moderate**



**Dr Strickler**

**Moderate**



**Dr Ciombor**

**Moderate**



**Dr Lieu**

**Less than that observed with other chemotherapy**



**Dr Mehta**

**Moderate**



**Dr Philip**

**Less than that observed with other chemotherapy**

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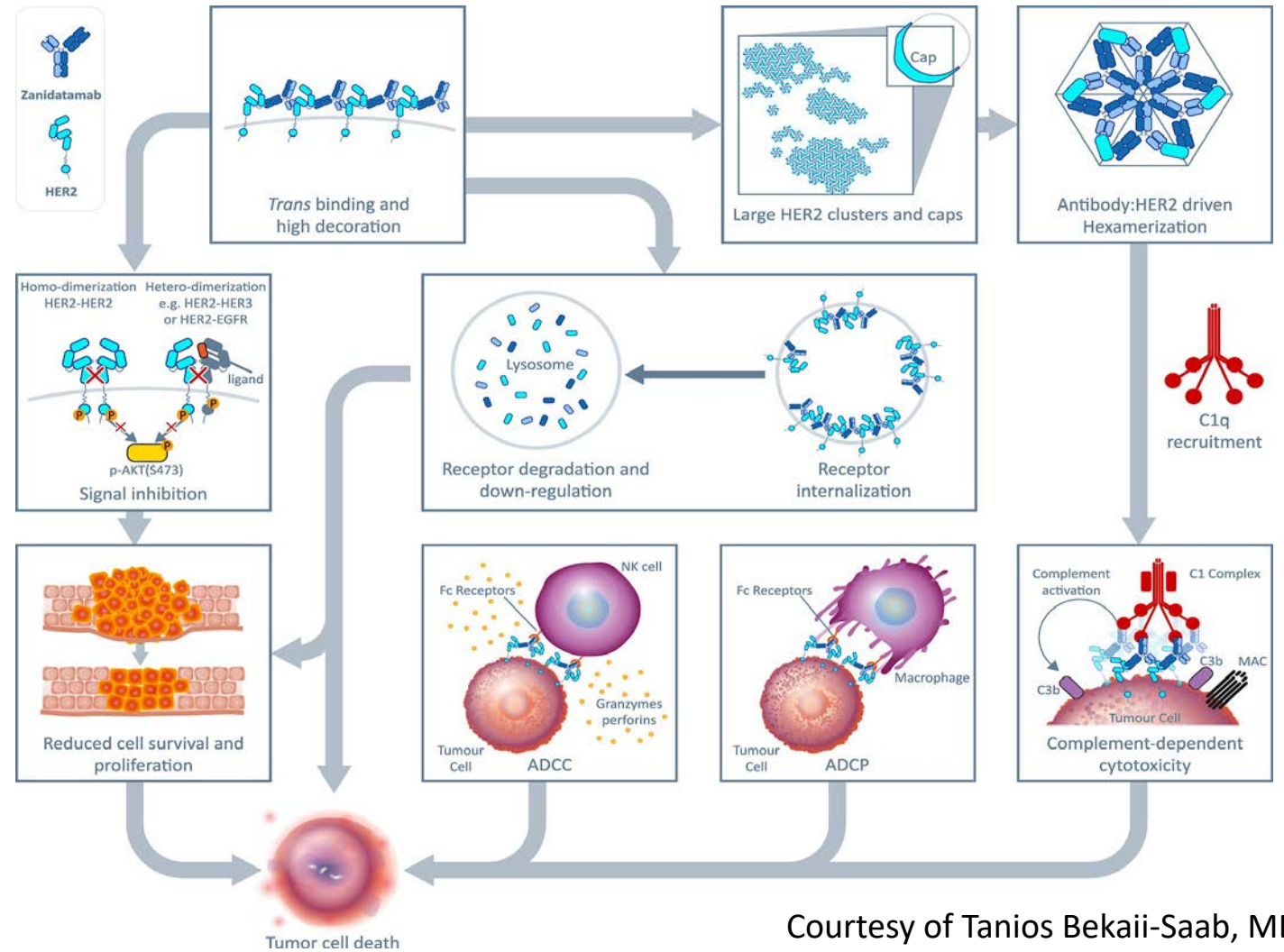
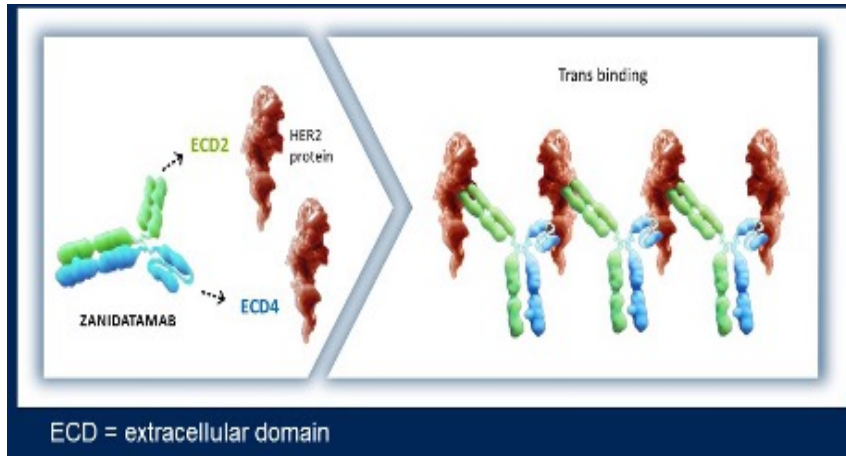
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Zanidatamab: anti-HER2 biparatopic antibody that induces unique HER2 clustering and complement-dependent cytotoxicity

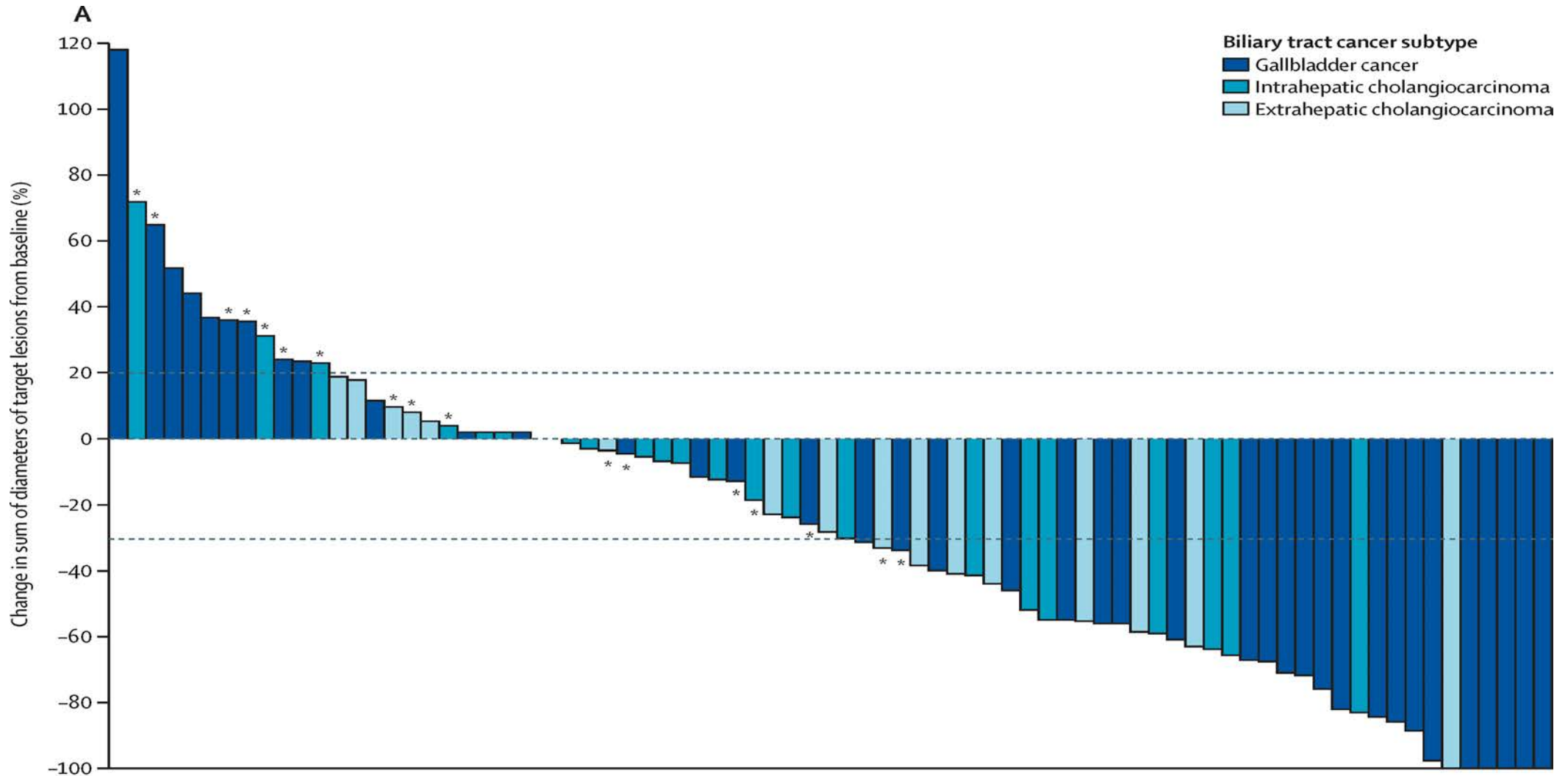


Courtesy of Tanios Bekaii-Saab, MD



# Zanidatamab for HER2-amplified, unresectable, locally advanced or metastatic biliary tract cancer (HERIZON-BTC-01): a multicentre, single-arm, phase IIb study

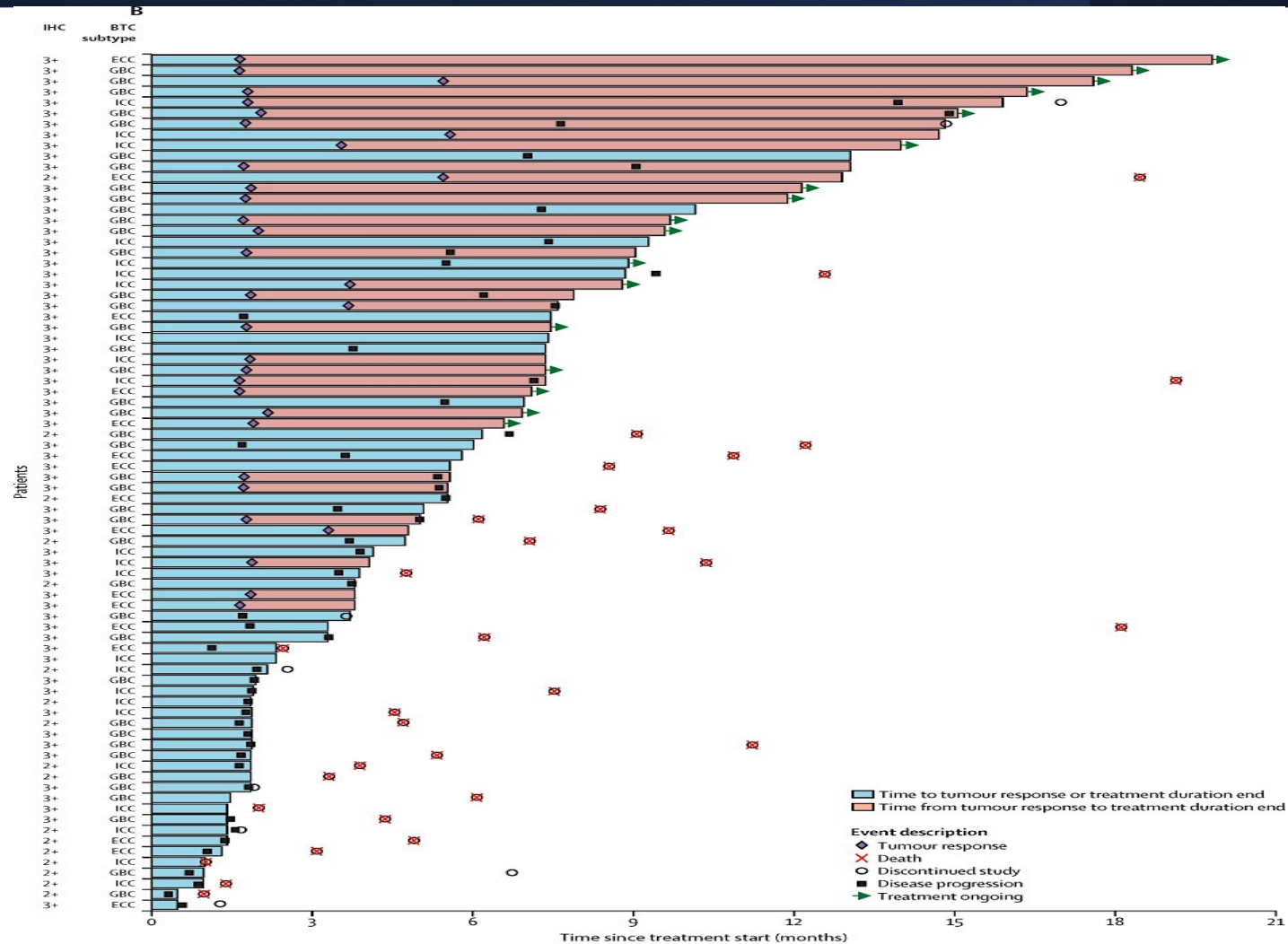
Harding J et al . Lancet Oncol 2023



Courtesy of Tanios Bekaii-Saab, MD

# Zanidatamab for HER2-amplified, unresectable, locally advanced or metastatic biliary tract cancer (HERIZON-BTC-01): a multicentre, single-arm, phase IIb study

Harding J et al . Lancet Oncol 2023



Courtesy of Tanios Bekaii-Saab, MD

# Inside the Issue: Optimizing the Diagnosis and Treatment of Neuroendocrine Tumors

*A CME/MOC-Accredited Live Webinar*

**Thursday, August 29, 2024**

**5:00 PM – 6:00 PM ET**

## **Faculty**

**Pamela Kunz, MD**

**Simron Singh, MD, MPH**

## **Moderator**

**Neil Love, MD**

***Thank you for joining us!***

***Please take a moment to complete the survey currently up on Zoom. Your feedback is very important to us. The survey will remain open for 5 minutes after the meeting ends.***

***Information on how to obtain CME, ABIM MOC and ABS credit is provided in the Zoom chat room. Attendees will also receive an email in 1 to 3 business days with these instructions.***