# Consensus or Controversy? Clinical Investigator Perspectives on the Current and Future Management of Hepatocellular Carcinoma and Pancreatic Cancer

**Wednesday, August 4, 2021**
**5:00 PM – 6:00 PM ET**

## Faculty

**Tanios Bekaii-Saab, MD**
**Kim A Reiss Binder, MD**
**Eileen M O'Reilly, MD**
**Philip A Philip, MD, PhD, FRCP**

## Moderator

**Neil Love, MD**

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Program Leader, Gastrointestinal Cancer
Mayo Clinic Cancer Center
Consultant, Mayo Clinic in Arizona
Phoenix, Arizona

**Kim A Reiss Binder, MD**
Assistant Professor
Abramson Cancer Center
University of Pennsylvania
Philadelphia, Pennsylvania

**Eileen M O'Reilly, MD**
Winthrop Rockefeller Endowed Chair in Medical Oncology
Section Head, Hepatopancreaticobiliary and Neuroendocrine Cancers
Co-Director, Medical Initiatives
David M Rubenstein Center for Pancreatic Cancer Research
Attending Physician, Member
Memorial Sloan Kettering Cancer Center
Professor of Medicine, Weill Cornell Medical College
New York, New York

**Philip A Philip, MD, PhD, FRCP**
Kathryn Cramer Endowed Chair in Cancer Research
Professor of Oncology and Pharmacology
Leader, GI and Neuroendocrine Oncology
Karmanos Cancer Institute
Wayne State University
Detroit, Michigan

## Moderator

**Neil Love, MD**
Research To Practice
Miami, Florida

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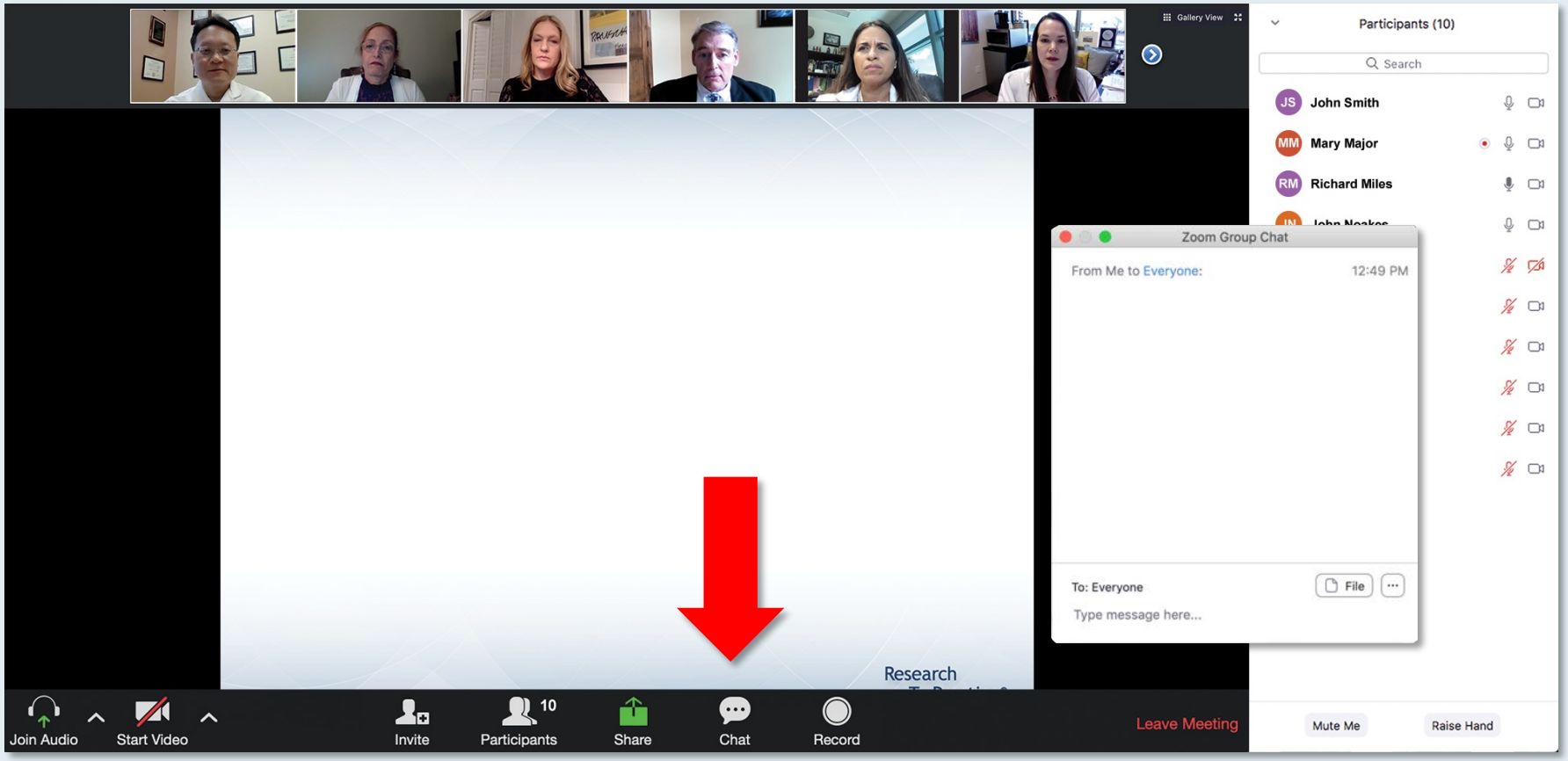


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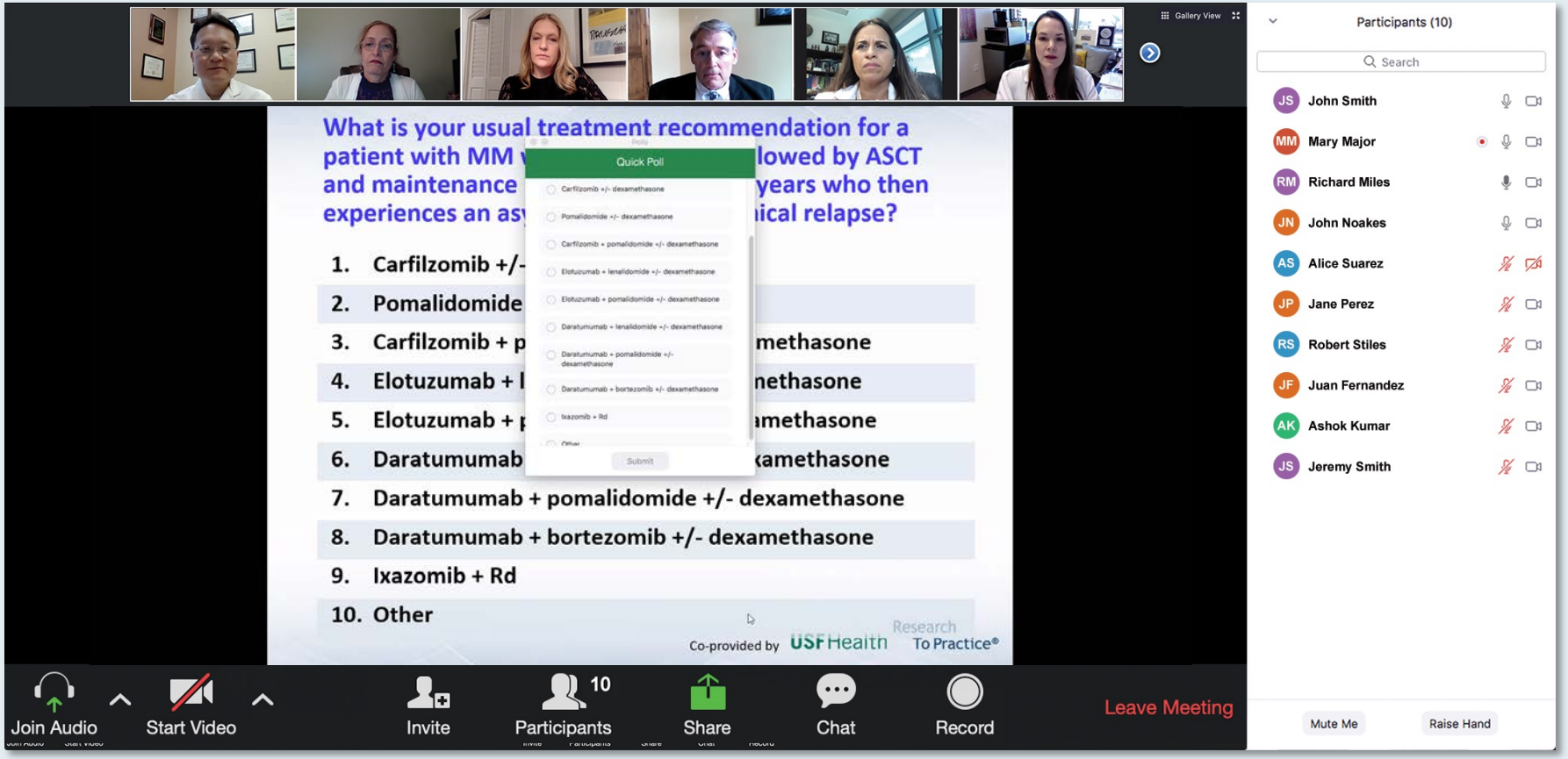
# Familiarizing Yourself with the Zoom Interface

## How to answer poll questions

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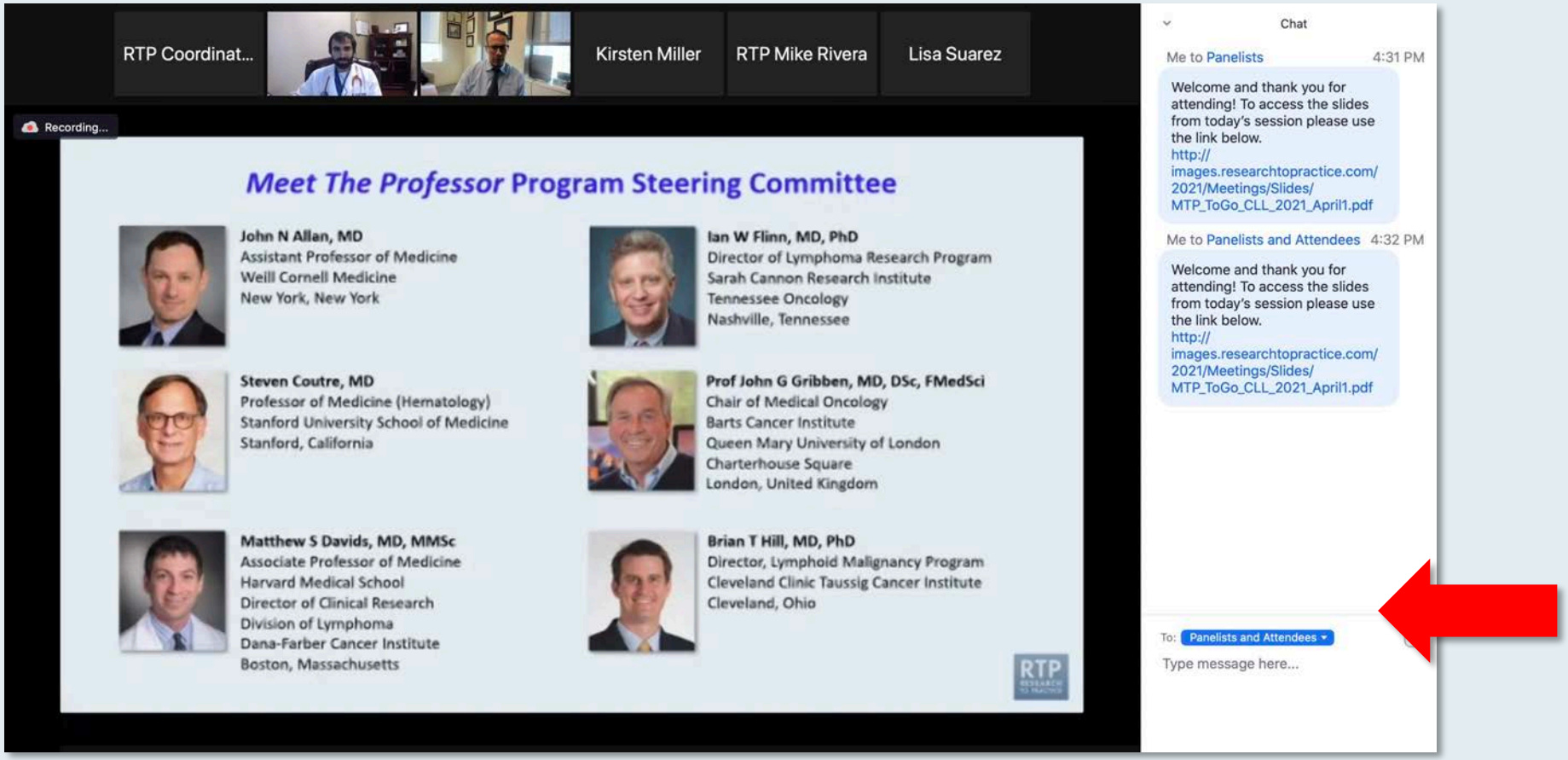
## Expand chat submission box




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

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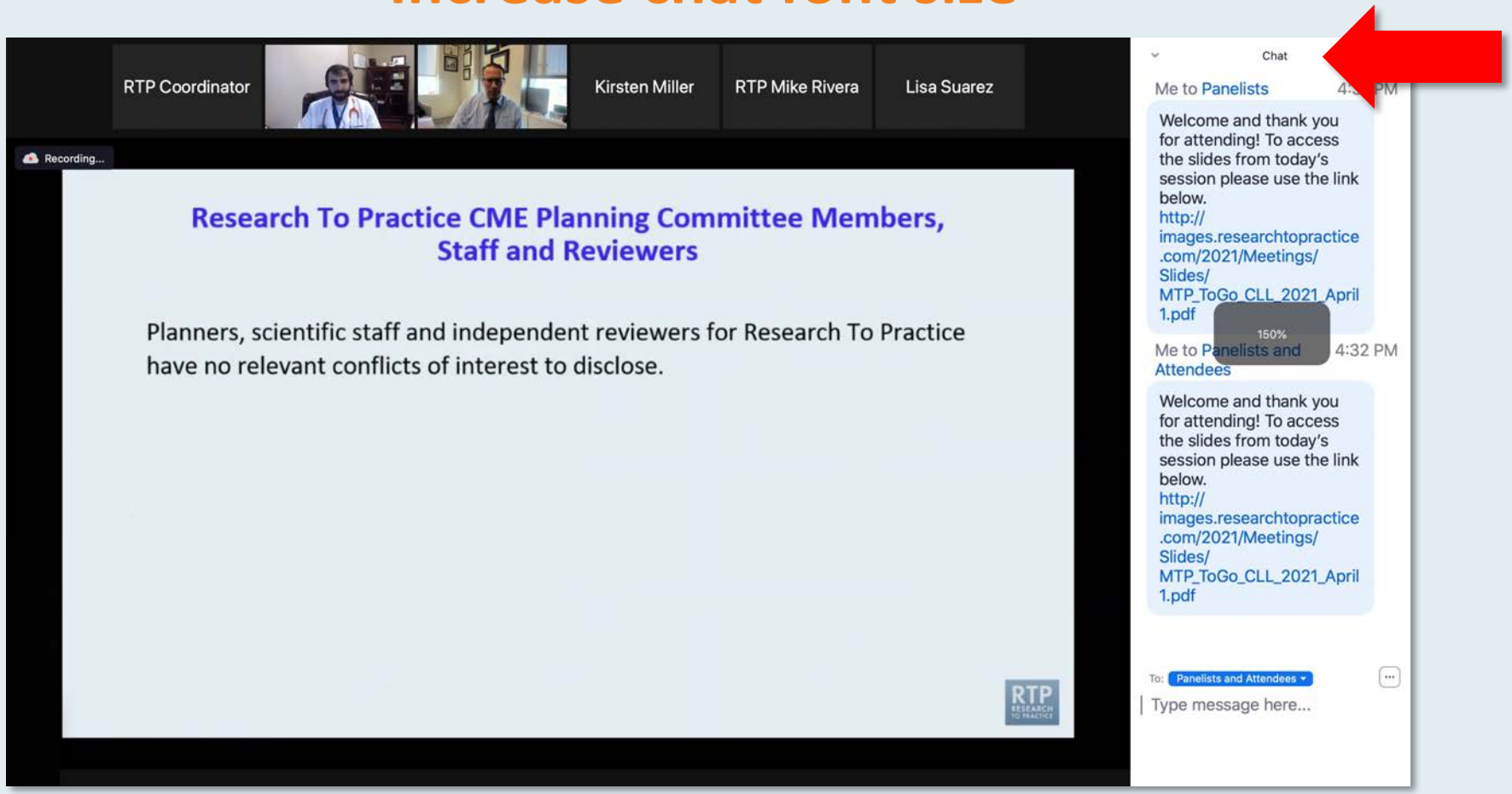


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# Advances in the Management of Cholangiocarcinoma


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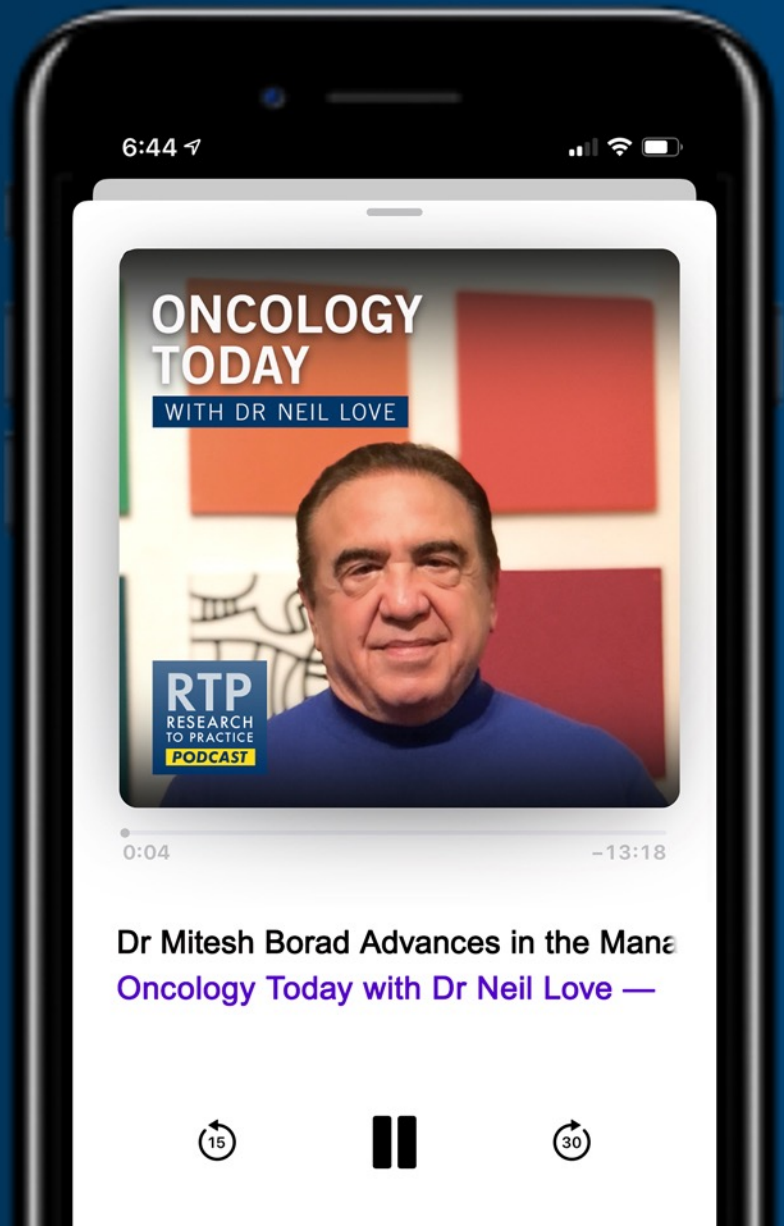

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# Chronic Lymphocytic Leukemia

**Thursday, August 5, 2021**
**5:00 PM – 6:00 PM ET**

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**John M Pagel, MD, PhD**
**Lesley Camille Ballance, MSN, FNP-BC**

## Moderator

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*Thank you for joining us!*

*CME and MOC credit information will be emailed to each participant within 2-3 business days.*

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Miami, Florida

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# *Consensus or Controversy* Consulting Investigators

**Dustin Deming, MD**
**University of Wisconsin**

**Eric Van Cutsem, MD, PhD**
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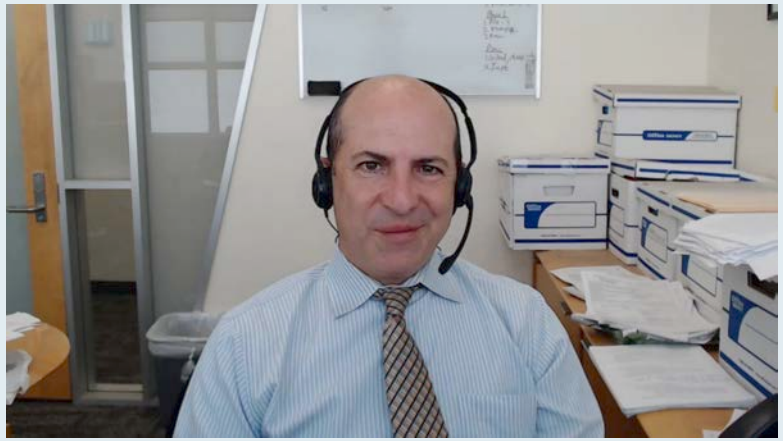

**Zev Wainberg, MD, MSc**
**UCLA School of Medicine**

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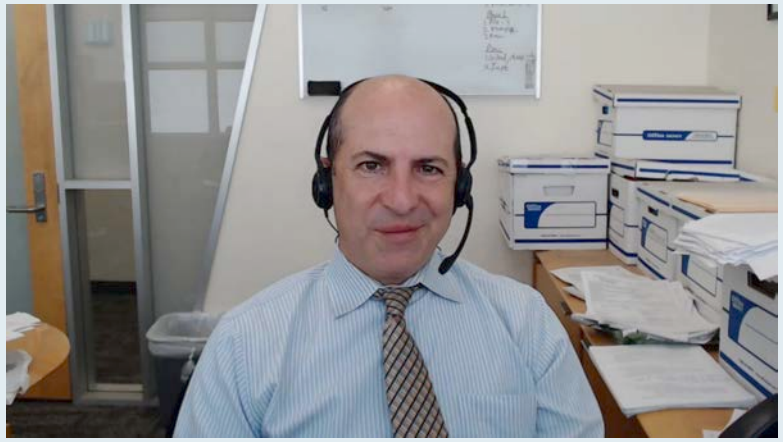

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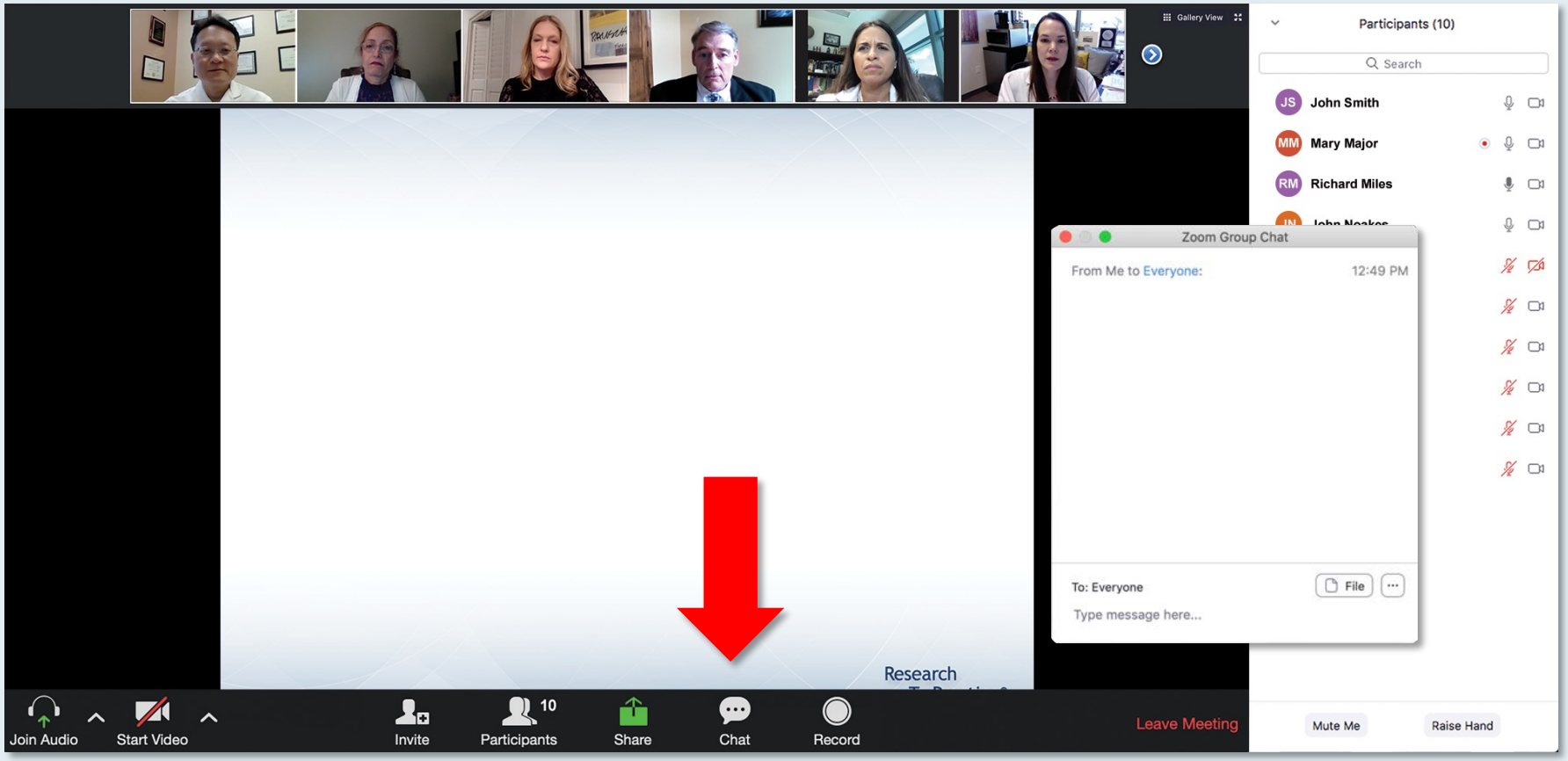


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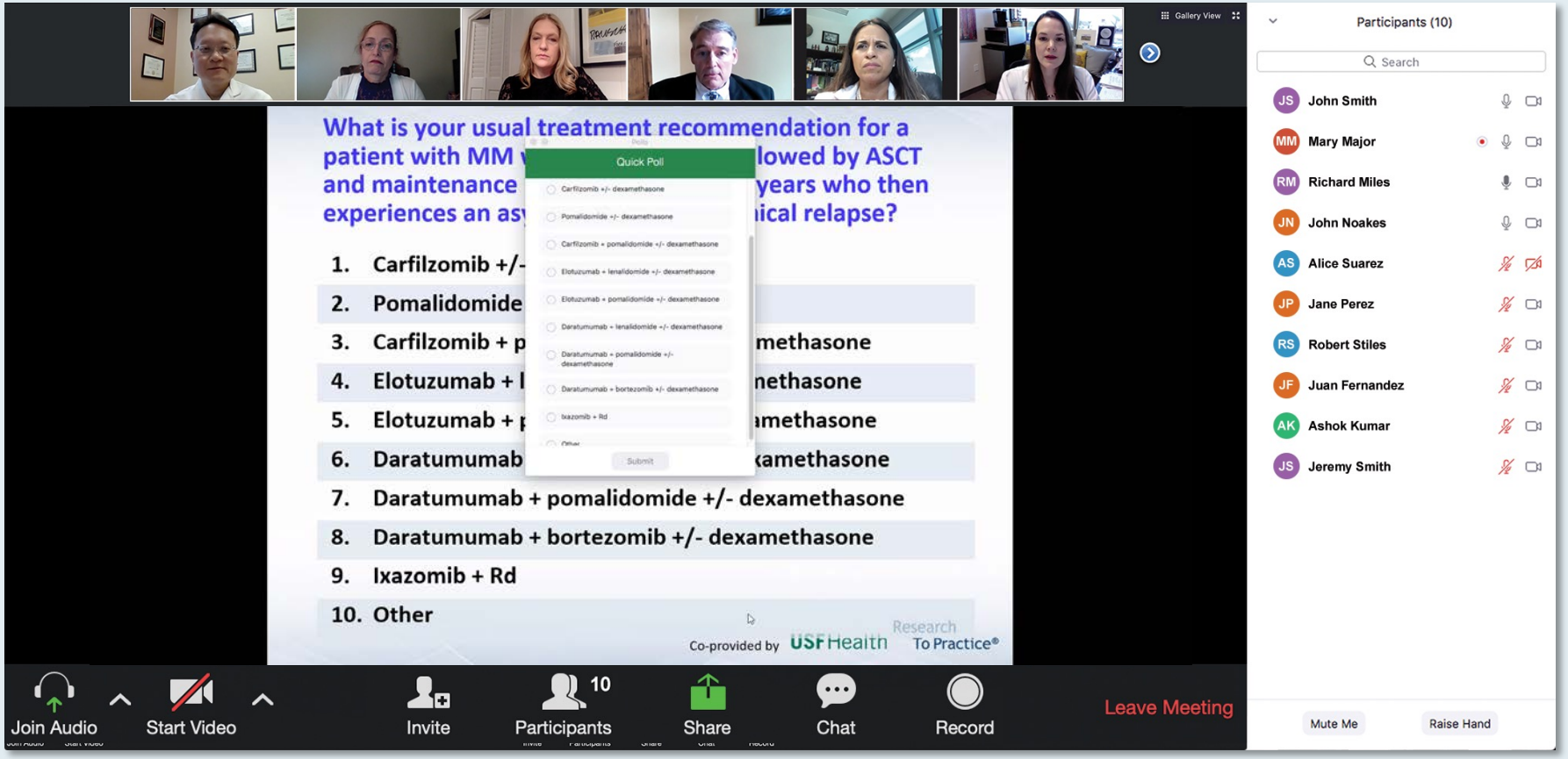


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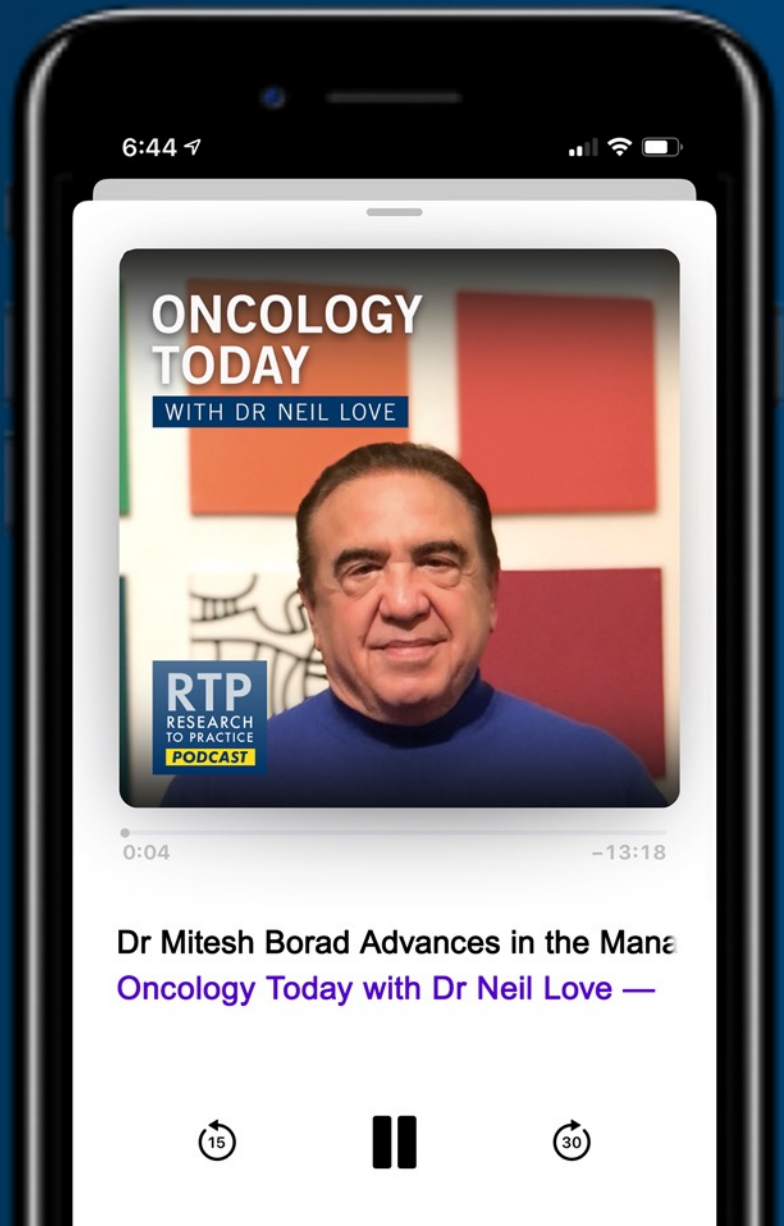

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# ASCO 2021 Hepatocellular Carcinoma and Pancreatic Cancer Presentation Library

## Selection and Sequencing of Therapy for Patients with Advanced Hepatocellular Carcinoma (HCC)

**Philip A Philip, MD, PhD, FRCP**

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## New Data Sets Investigating Novel Treatment Strategies for Advanced Biliary Tract Cancers

**Tanios Bekaii-Saab, MD**

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## Optimal Management of Localized and Advanced Pancreatic Cancer

**Eileen M O'Reilly, MD**

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## Considerations in the Use of PARP Inhibitors in Patients with Advanced Pancreatic Cancer

**Kim A Reiss Binder, MD**

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**Selection and Sequencing of Treatment for Advanced Gastroesophageal Cancers**

**Zev Wainberg, MD, MSc**

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**Recent Advances in the Management of HER2-Positive Advanced Gastric Cancer; Other Promising Targeted Strategies**

**Eric Van Cutsem, MD, PhD**

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**Incorporation of Immunotherapy and HER2-Targeted Therapy into the Management of Metastatic Colorectal Cancer (mCRC)**

**Dustin Deming, MD**

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**Other Considerations in the Treatment of mCRC: Cytotoxics, Biologics and RAS/RAF-Targeted Therapies**

**Chloe E Atreya, MD, PhD**

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# Agenda

## Interdisciplinary Care: Supportive, Palliative and Complementary Strategies – Part 1

## Module 1: Hepatocellular Carcinoma (HCC)

- What is the optimal first-line systemic treatment for advanced HCC with Child-Pugh A and B cirrhosis?
- What is the optimal second-line systemic treatment for advanced HCC after atezolizumab/bevacizumab?

## Interdisciplinary Care: Supportive, Palliative and Complementary Strategies – Part 2

## Module 2: Pancreatic Cancer

- In what situations, if any, do you utilize neoadjuvant chemotherapy for patients with potentially resectable primary pancreatic cancer?
- What is your current adjuvant systemic treatment for pancreatic cancer and first-line treatment for metastatic disease?
- In which clinical scenarios should germline and/or somatic genomic testing be done in patients with pancreatic cancer?
- What is the current and future role of PARP inhibitors in the treatment of pancreatic cancer?

## Interdisciplinary Care: Supportive, Palliative and Complementary Strategies – Part 3

## Module 3: Cholangiocarcinoma

- What somatic and/or germline testing, if any, should be performed in cholangiocarcinoma?
- How often are FGFR2 translocations observed in cholangiocarcinoma? What are the risks and benefits of FGFR2 inhibitors?

# Agenda

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# Questions for the Faculty from Webinar Registrants – HCC

- **All the second-line FDA approvals in advanced HCC are based on sorafenib failure, do we have any data on patients who failed lenvatinib or bevacizumab/atezolizumab as first-line?**
- **How do you sequence therapy in HCC? There are so many choices — information overload — simplify please**
- **Best therapy for Child Pugh B/C patients?**
- **If progressed on bevacizumab/atezolizumab would you ever use another IO on these patients?**

Premeeting survey: July 2021

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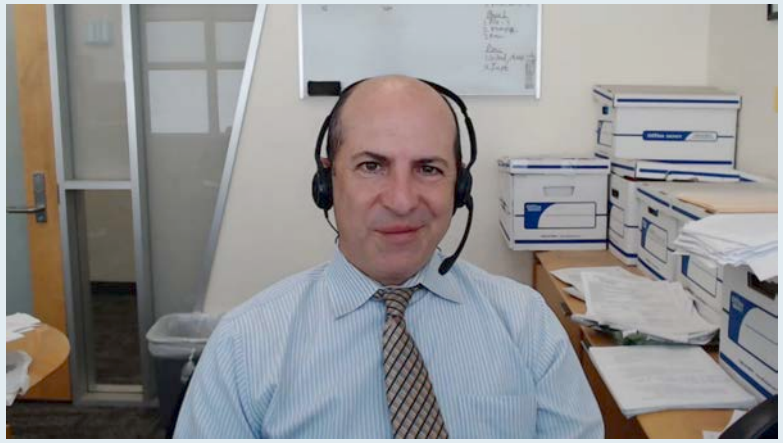
Prof Eric Van Cutsem

TikTonc



Dr Zev Wainberg

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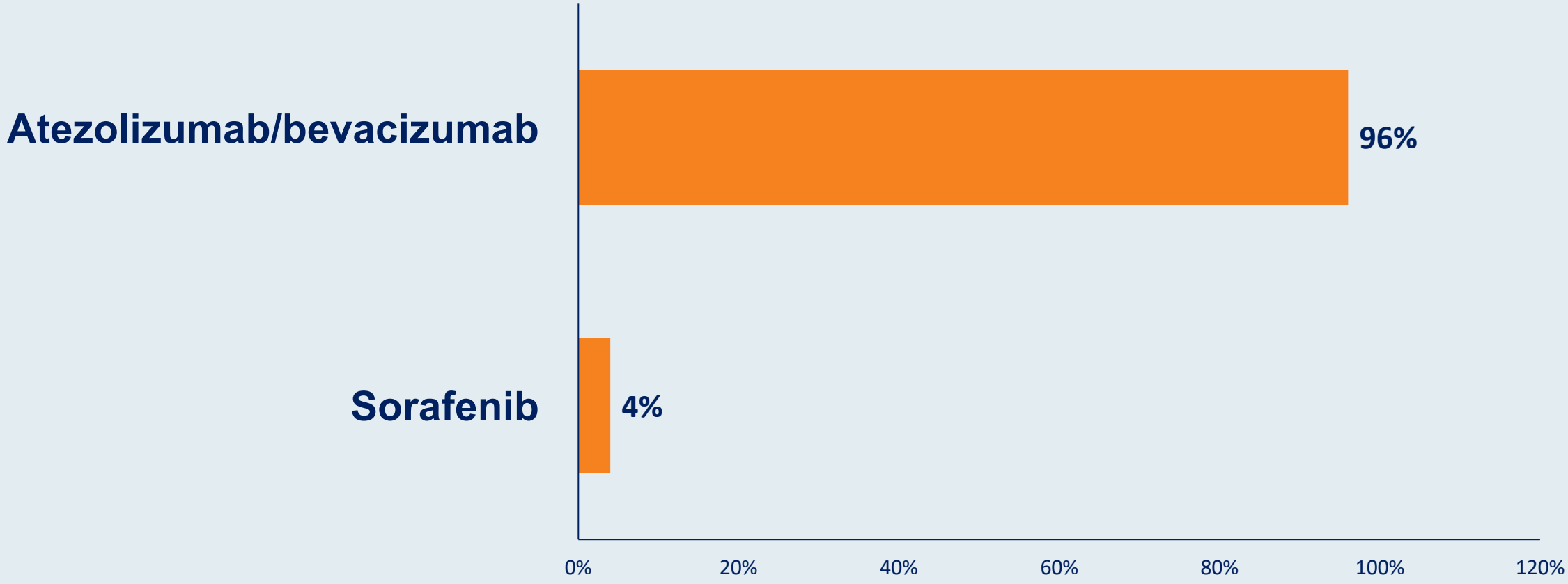
# What would be your current preferred first-line systemic treatment for a 65-year-old patient with hepatocellular carcinoma (HCC), a Child-Pugh A score and a PS of 0?




Premeeting survey: July 2021

RTP RESEARCH TO PRACTICE

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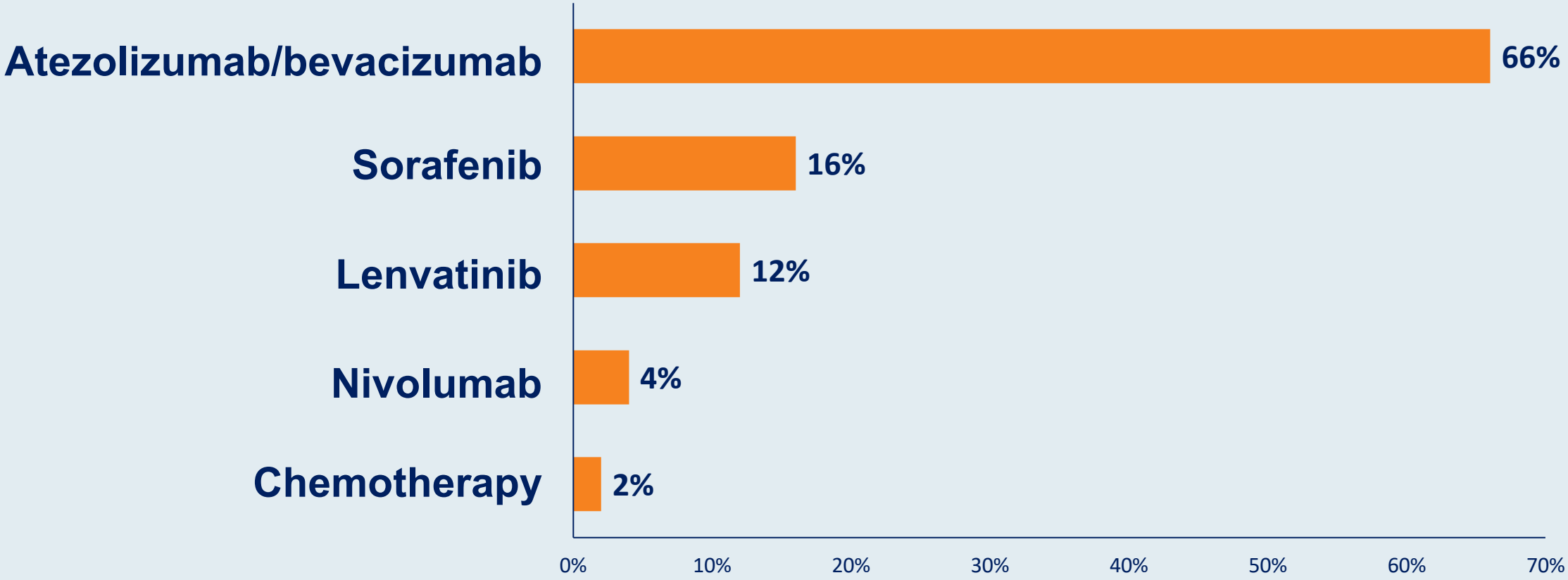
| | | | |
|---|---|---|---|
|  Dr Bekaii-Saab | Atezolizumab/ bevacizumab |  Dr Atreya | Atezolizumab/ bevacizumab |
|  Dr O'Reilly | Atezolizumab/ bevacizumab |  Dr Deming | Atezolizumab/ bevacizumab |
|  Dr Philip | Atezolizumab/ bevacizumab |  Prof Van Cutsem | Atezolizumab/ bevacizumab |
|  Dr Reiss Binder | Atezolizumab/ bevacizumab |  Dr Wainberg | Atezolizumab/ bevacizumab |

RTP RESEARCH TO PRACTICE

# What would be your current preferred first-line systemic treatment for a 78-year-old patient with HCC, a Child-Pugh B7 score and a PS of 1?




Premeeting survey: July 2021

RTP RESEARCH TO PRACTICE

# What would be your current preferred first-line systemic treatment for a 78-year-old patient with HCC, a Child-Pugh B7 score and a PS of 1?

| | |
|---|---|
|  Dr Bekaii-Saab | Atezolizumab/ bevacizumab |
|  Dr O'Reilly | Atezolizumab/ bevacizumab |
|  Dr Philip | Atezolizumab/ bevacizumab |
|  Dr Reiss Binder | Sorafenib |
|  Dr Atreya | Sorafenib |
|  Dr Deming | Sorafenib or nivolumab |
|  Prof Van Cutsem | Atezolizumab/ bevacizumab |
|  Dr Wainberg | Lenvatinib |

RTP RESEARCH TO PRACTICE

**Regulatory and reimbursement issues aside, what is the optimal first-line therapy for a patient with newly diagnosed HCC, and how do patient age/performance status and Child-Pugh score affect this decision?**

- IMbrave150 phase 3 trial established the superiority of atezolizumab plus bevacizumab over sorafenib with a favorable toxicity profile
- Older patients are still considered for active therapy if they have no major comorbidities such as CVS disease or uncontrolled varices
- Child-Pugh score is highly prognostic and related to tolerance to therapy but may not be predictive of benefit
- In general, Child-Pugh B patients may be considered for systemic treatment but not those with Child-Pugh C
- Patients with PS 3-4 (BCLC-D) are not candidates for systemic therapy

**Under what circumstances do you recommend multikinase inhibitor monotherapy to your patients with newly diagnosed HCC? When you treat a patient with a multikinase inhibitor in the first-line setting, how do you select between sorafenib and lenvatinib?**

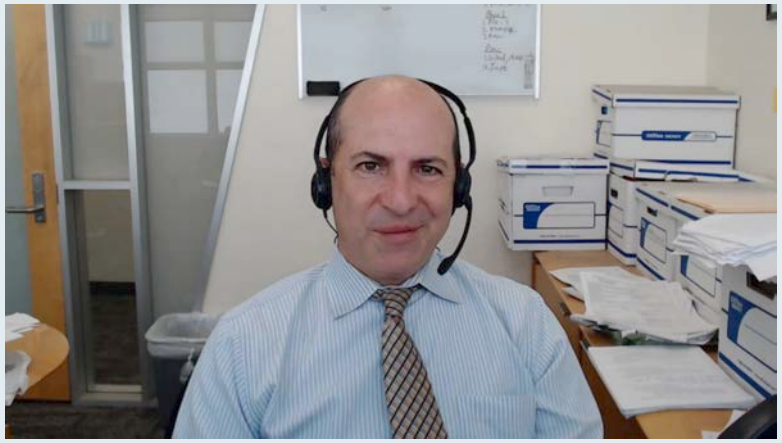
- Sorafenib or lenvatinib is used if there are contraindications to receiving Atezo/bev or patient preference
- Phase 3 trial comparing lenvatinib to sorafenib showed non-inferiority with similar OS outcomes
- Choice may be influenced by comorbidities such as uncontrolled hypertension or patient preference
- Lenvatinib may be favored given PFS and objective response superiority over sorafenib

# What is the optimal second-line systemic treatment for advanced HCC after atezolizumab/bevacizumab?

Dr Dustin Deming

Prof Eric Van Cutsem

TikTonc



Dr Zev Wainberg

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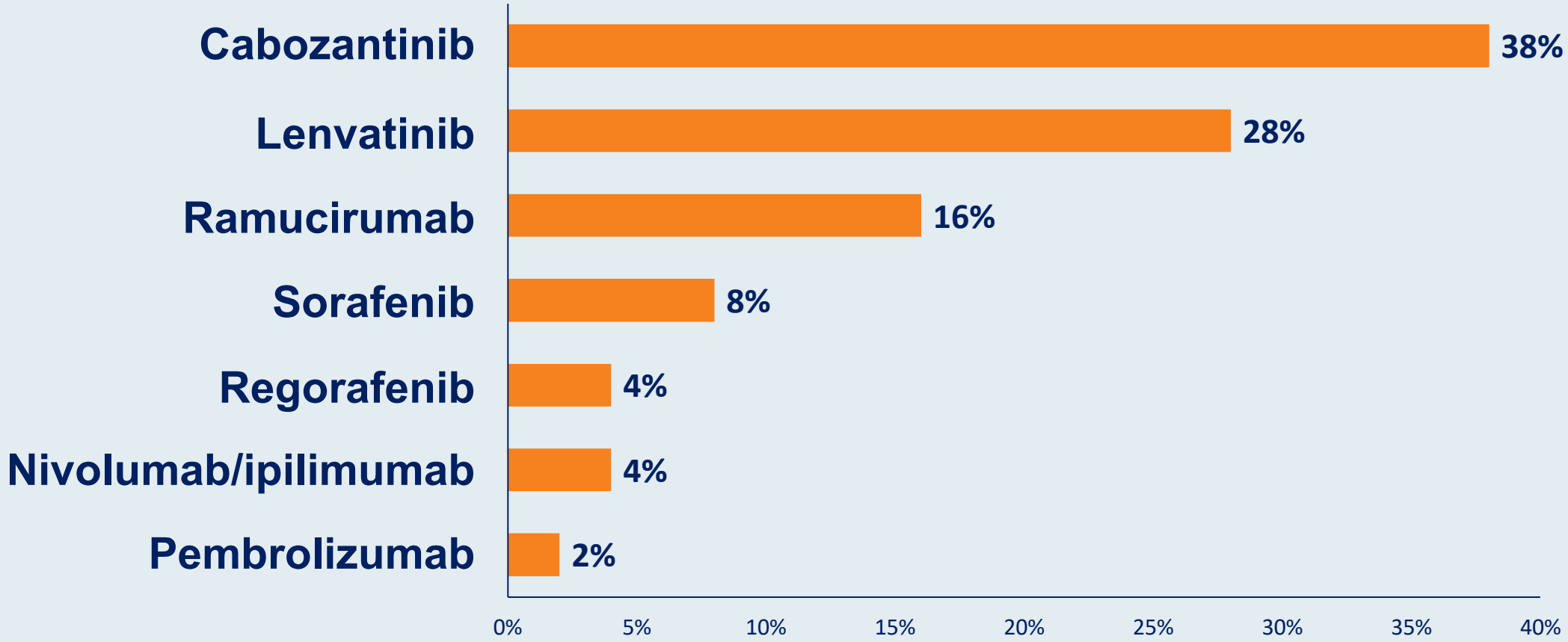
# What would be your most likely second-line systemic therapy for a 65-year-old patient with HCC, a Child-Pugh A score and a PS of 0 who received first-line atezolizumab/bevacizumab with minimal toxicity, had stable disease for 14 months and then experienced disease progression (AFP = 2,500 ng/mL)?




Premeeting survey: July 2021

RTP RESEARCH TO PRACTICE

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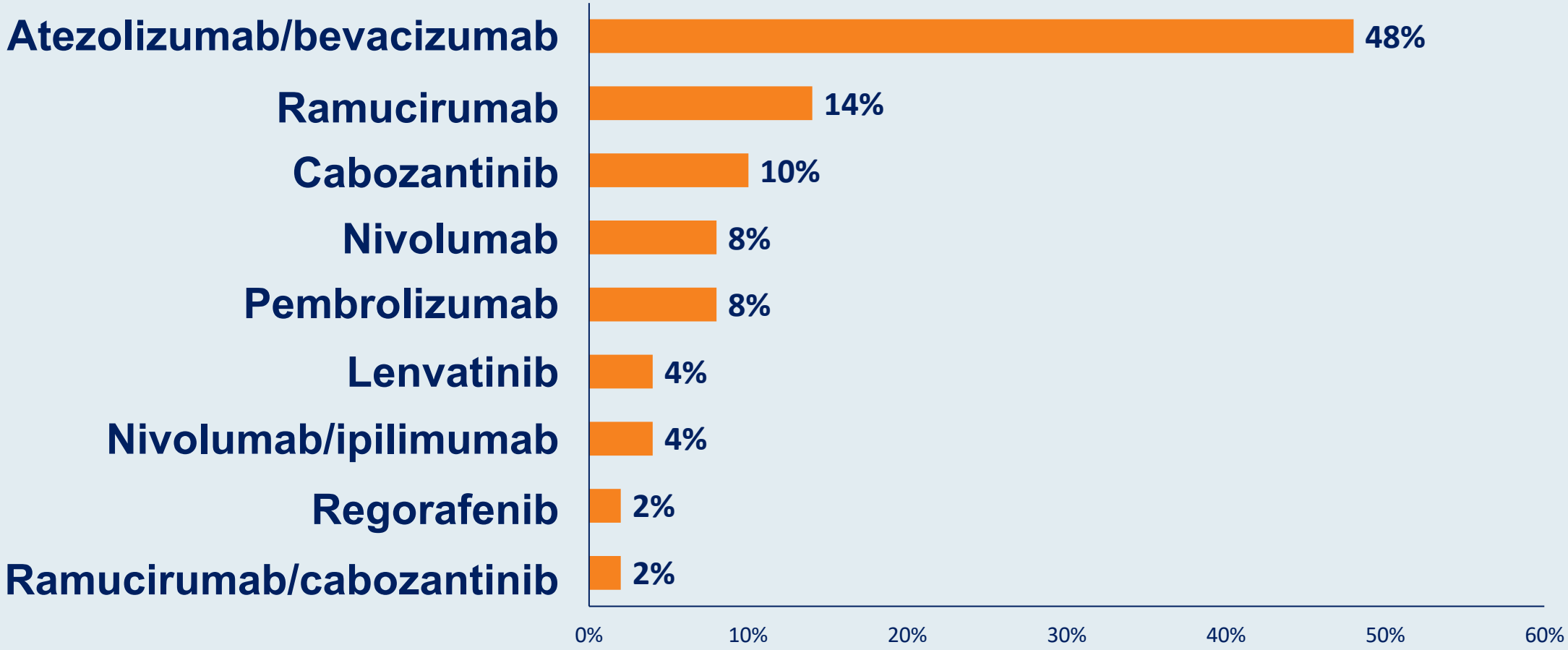
| | | | |
|---|---|---|---|
|  Dr Bekaii-Saab | Cabozantinib |  Dr Atreya | Ramucirumab or Nivolumab/ipilimumab |
|  Dr O'Reilly | Lenvatinib |  Dr Deming | Lenvatinib |
|  Dr Philip | Lenvatinib |  Prof Van Cutsem | Sorafenib or Lenvatinib |
|  Dr Reiss Binder | Cabozantinib |  Dr Wainberg | Lenvatinib |

RTP RESEARCH TO PRACTICE

# What would be your most likely second-line systemic therapy for a 65-year-old patient with HCC, a Child-Pugh A score and a PS of 0 who received first-line standard-dose sorafenib with minimal toxicity, had stable disease for 14 months and then experienced disease progression (AFP = 2,500 ng/mL)?




Premeeting survey: July 2021

RTP RESEARCH TO PRACTICE

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| | | | |
|---|---|---|---|
|  Dr Bekaii-Saab | Atezolizumab/ bevacizumab |  Dr Atreya | Atezolizumab/ bevacizumab |
|  Dr O'Reilly | Atezolizumab/ bevacizumab |  Dr Deming | Atezolizumab/ bevacizumab |
|  Dr Philip | Regorafenib |  Prof Van Cutsem | Ramucirumab |
|  Dr Reiss Binder | Atezolizumab/ bevacizumab |  Dr Wainberg | Atezolizumab/ bevacizumab |

RTP RESEARCH TO PRACTICE

**How do factors such as prior systemic therapy, duration of response, liver function, presence of comorbidities and AFP level influence your selection and sequencing of second- and later-line therapy for patients with relapsed HCC?**

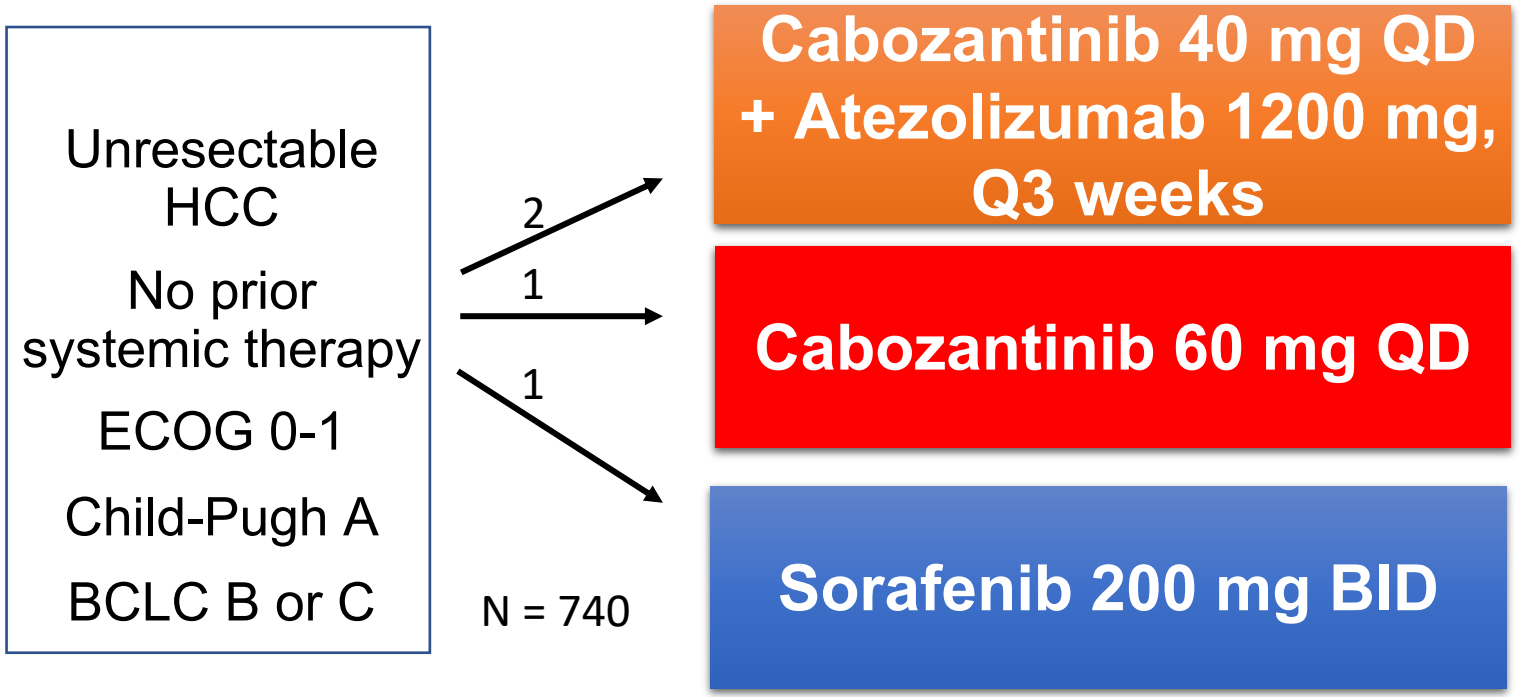
- The strategy should be exposure to different classes of drugs that include IO, TKI, and anti-VEGF/VEGFR antibodies
- Frontline Atezo/bev or TKI dictates subsequent therapies
- TKIs share VEGR inhibition but have their own profiles of kinase inhibition which make cross resistance and toxicity less likely
- Ramucirumab is indicated if AFP $\geq$400 and is probably better tolerated than TKI in moderate to severe liver dysfunction

# Questions for the Faculty from Webinar Registrants – HCC

- **Atezolizumab/bevacizumab versus TACE for liver localized disease?**
- **How often do you see lenvatinib 8mg dose working? I typically cannot get patients above 8mg due to toxicity**
- **Approach to patients with prior liver transplant?**

Premeeting survey: July 2021

# Frontline Phase 3 trial of Cabozantinib plus atezolizumab versus sorafenib in unresectable HCC- COSMIC-312 trial




**"2021 press release"**

- **PFS endpoint met HR 0.63, p = 0.0012**
- **OS trending, NS**

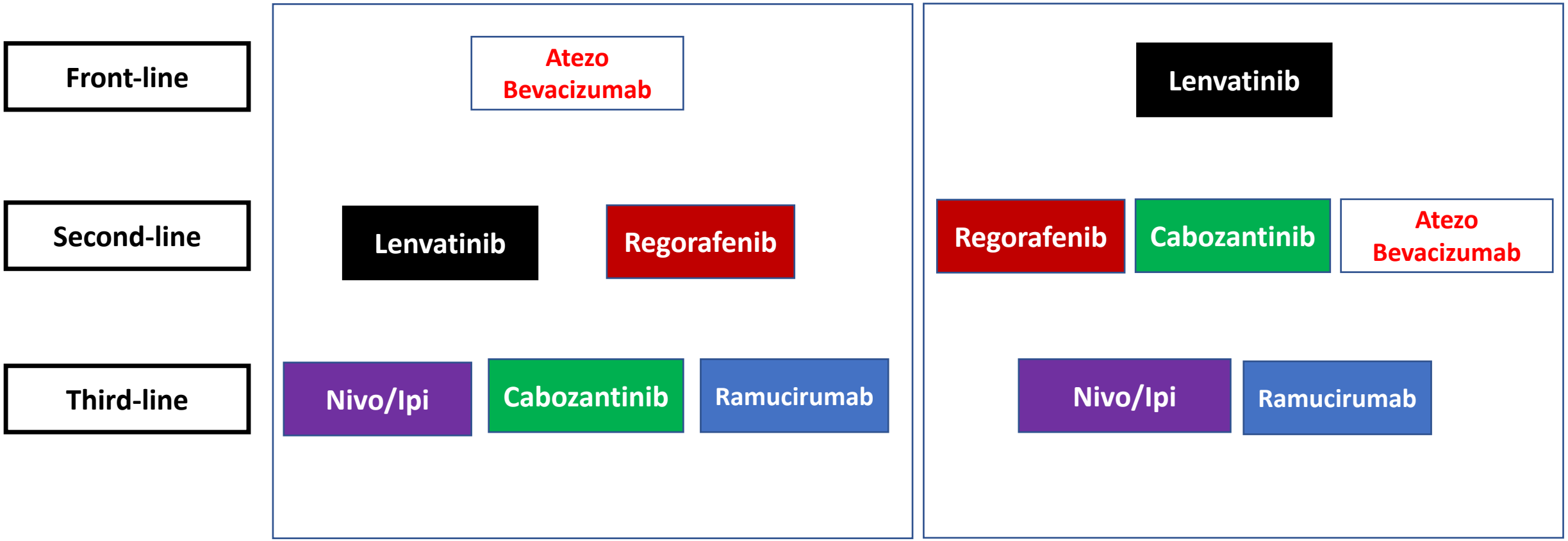
- Co-Primary endpoint PFS and OS
- Stratified by region, MVI/EHS, ECOG PS, AFP (< 400 ng/mL vs ≥ 400 ng/mL), and geography

NCT03755791

Kelley RK, et al. Future Oncol, 2020

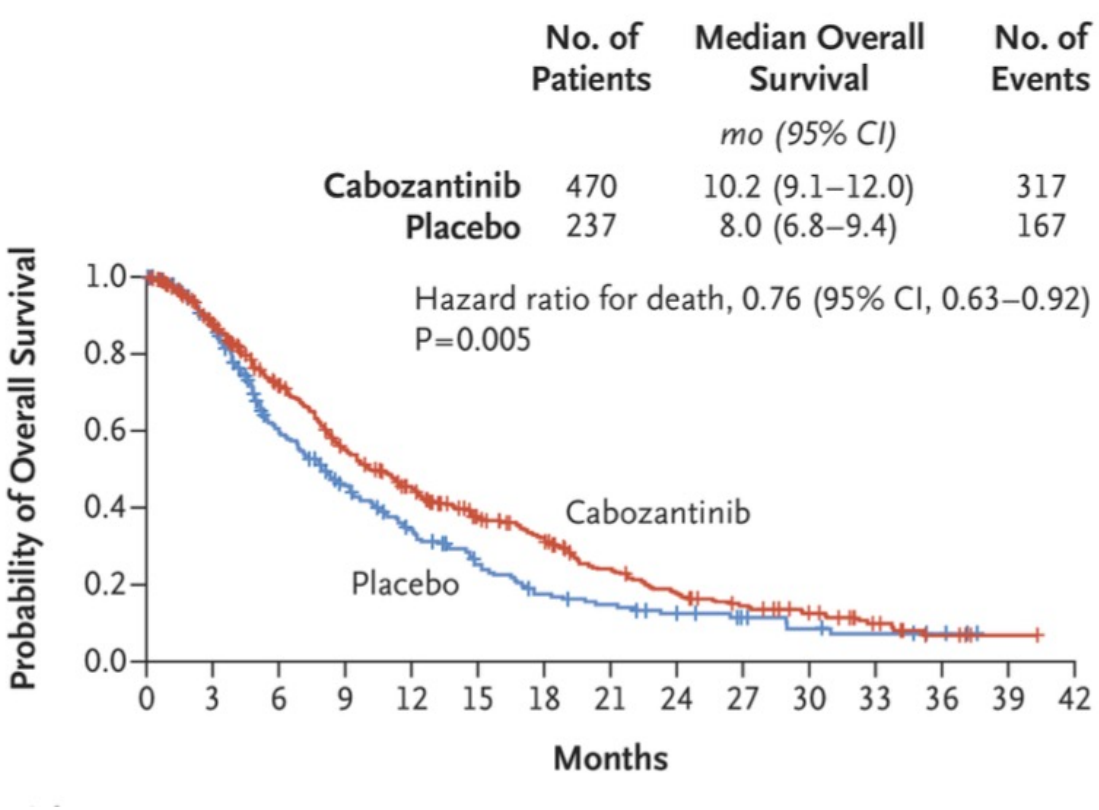
Courtesy of Philip A Philip, MD, PhD, FRCP

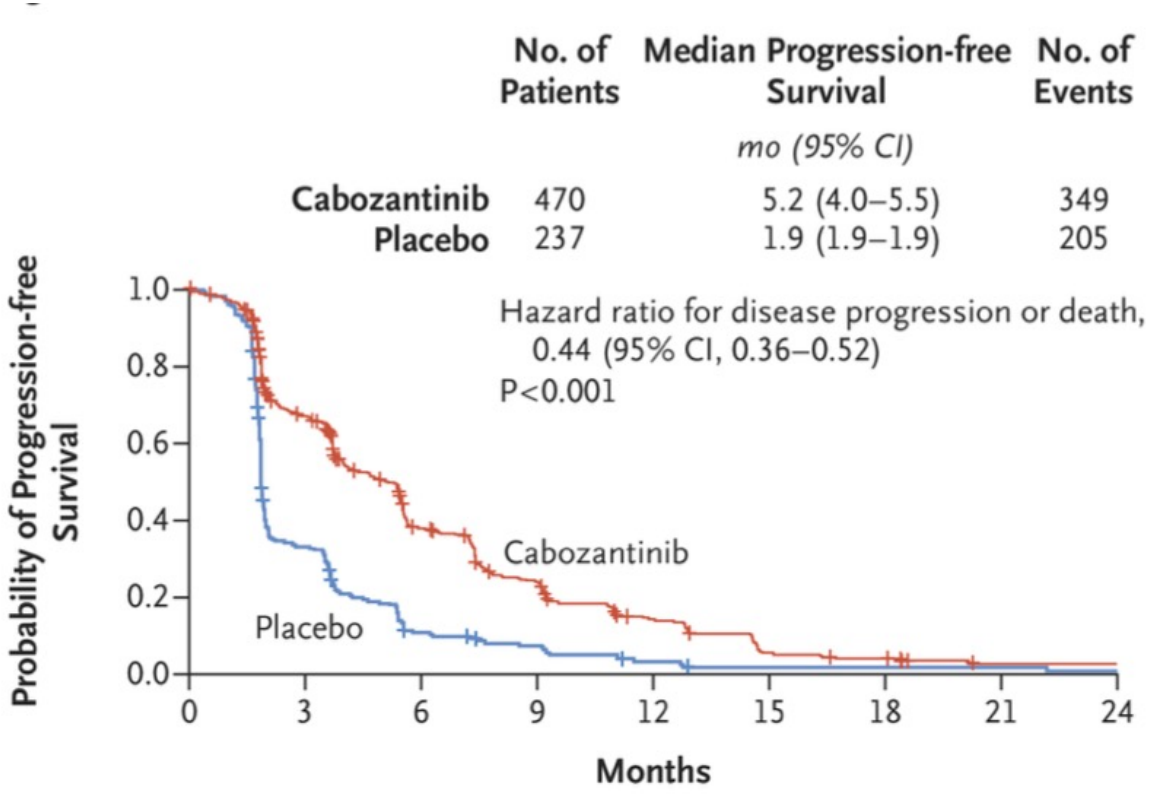
# Sequencing to take into account exposure to all classes of drugs




Courtesy of Philip A Philip, MD, PhD, FRCP

# CELESTIAL: Cabozantinib improved both overall survival & progression free survival after failure on 1-2 prior treatments

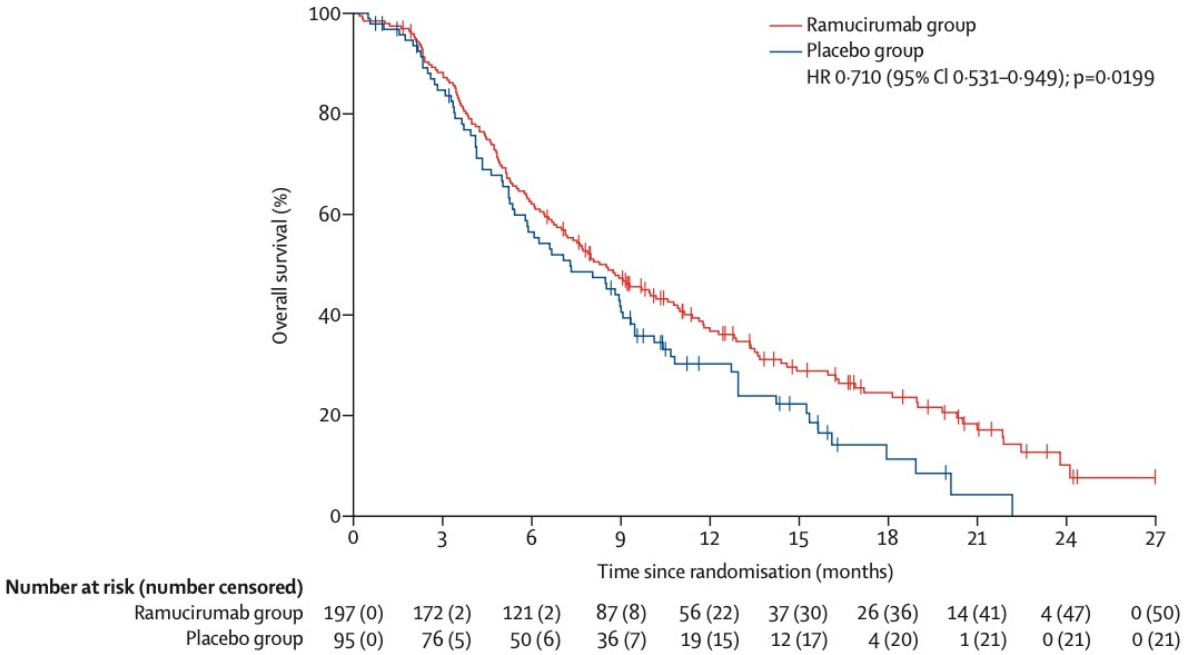


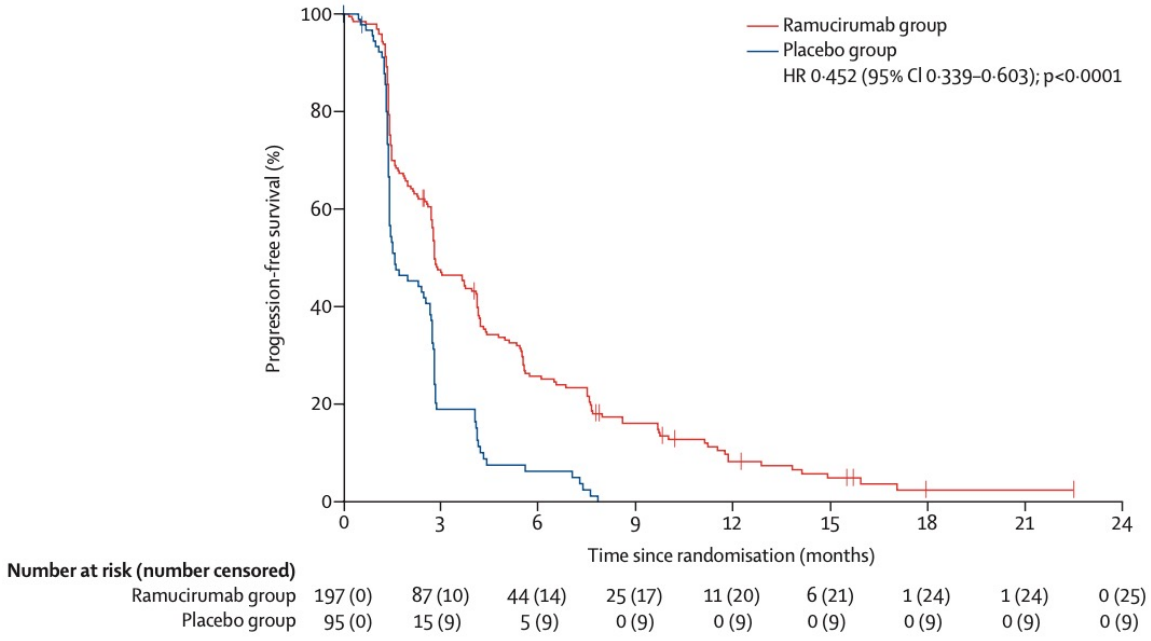




Abou-Alfa GK, et al, NEJM, 379:54-63, 2018

Courtesy of Philip A Philip, MD, PhD, FRCP

# REACH-2: Overall and progression free survival were significantly prolonged with ramucirumab




Zhu et al, The Lancet, 2019

Courtesy of Philip A Philip, MD, PhD, FRCP

# Agenda

## Interdisciplinary Care: Supportive, Palliative and Complementary Strategies – Part 1

### Module 1: Hepatocellular Carcinoma (HCC)

- What is the optimal first-line systemic treatment for advanced HCC with Child-Pugh A and B cirrhosis?
- What is the optimal second-line systemic treatment for advanced HCC after atezolizumab/bevacizumab?

## Interdisciplinary Care: Supportive, Palliative and Complementary Strategies – Part 2

### Module 2: Pancreatic Cancer

- In what situations, if any, do you utilize neoadjuvant chemotherapy for patients with potentially resectable primary pancreatic cancer?
- What is your current adjuvant systemic treatment for pancreatic cancer and first-line treatment for metastatic disease?
- In which clinical scenarios should germline and/or somatic genomic testing be done in patients with pancreatic cancer?
- What is the current and future role of PARP inhibitors in the treatment of pancreatic cancer?

## Interdisciplinary Care: Supportive, Palliative and Complementary Strategies – Part 3

### Module 3: Cholangiocarcinoma

- What somatic and/or germline testing, if any, should be performed in cholangiocarcinoma?
- How often are FGFR2 translocations observed in cholangiocarcinoma? What are the risks and benefits of FGFR2 inhibitors?

# Agenda

## Interdisciplinary Care: Supportive, Palliative and Complementary Strategies – Part 1

## Module 1: Hepatocellular Carcinoma (HCC)

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RTP RESEARCH TO PRACTICE

# Questions for the Faculty from Webinar Registrants – Pancreatic Cancer

- **New treatments in pipeline for pancreatic cancer?**
- **Do you trust CT restaging monitoring the response of unresectable pancreatic cancer or do you need PETFDG scan baseline and to monitor the response?**
- **For a patient who is borderline resectable, after how many cycles of chemotherapy would you decide that they will not achieve resectability?**
- **How do you typically dose gemcitabine/*nab* paclitaxel?**
- **Role for KRAS inhibitors G12A, C or D? What trials are available and any opinion if they show promise?**
- **Elderly metastatic pancreatic with progression on gemcitabine/*nab*-paclitaxel. Performance ECOG 1. Grade 1 neuropathy. Second line therapy choice?**

Premeeting survey: July 2021

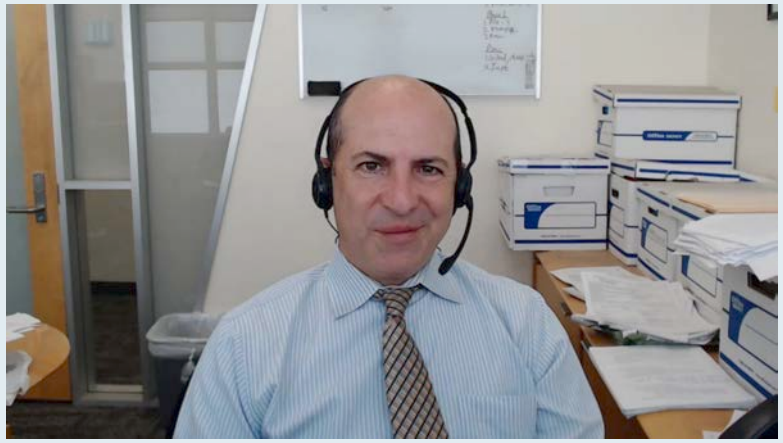
RTP RESEARCH TO PRACTICE

# In what situations, if any, do you utilize neoadjuvant chemotherapy for patients with potentially resectable primary pancreatic cancer?

Dr Dustin Deming

Prof Eric Van Cutsem

TikTonc



Dr Zev Wainberg

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# What neoadjuvant systemic therapy would you recommend for a 78-year-old patient with borderline resectable pancreatic cancer?

| | | | |
|---|---|---|---|
|  Dr Bekaii-Saab | *Nab* paclitaxel/ gemcitabine biweekly |  Dr Atreya | *Nab* paclitaxel/ gemcitabine |
|  Dr O'Reilly | mFOLFIRINOX or *nab* paclitaxel/gemcitabine |  Dr Deming | *Nab* paclitaxel/ gemcitabine |
|  Dr Philip | *Nab* paclitaxel/ gemcitabine |  Prof Van Cutsem | *Nab* paclitaxel/ gemcitabine |
|  Dr Reiss Binder | mFOLFIRINOX |  Dr Wainberg | mFOLFIRINOX |

mFOLFIRINOX = modified FOLFIRINOX

RTP RESEARCH TO PRACTICE

# What is your likely adjuvant systemic therapy recommendation for an otherwise healthy 78-year-old patient who is s/p surgical resection of pancreatic adenocarcinoma?

| | | | |
|---|---|---|---|
|  Dr Bekaii-Saab | Gemcitabine/ capecitabine |  Dr Atreya | Gemcitabine/ capecitabine or Gemcitabine/*nab* paclitaxel |
|  Dr O'Reilly | Modified FOLFIRINOX |  Dr Deming | Gemcitabine/*nab* paclitaxel |
|  Dr Philip | Gemcitabine |  Prof Van Cutsem | Gemcitabine |
|  Dr Reiss Binder | Modified FOLFIRINOX |  Dr Wainberg | Modified FOLFIRINOX |

RTP RESEARCH TO PRACTICE

## Under what circumstances should patients with resectable pancreatic adenocarcinoma (PAD) be offered neoadjuvant treatment (NT)?

- All patients by default should be considered for NT
  - Exceptions may include very small tumors , LN-, normal CA 19-9 and minimal to no symptoms
- Optimal NT regimen yet to be defined
  - ? Role of radiation therapy?
- Consideration for biomarkers + a rationale for switch NT under study

# What is the Optimal Approach to Neoadjuvant Therapy: Borderline Resectable PDAC? How do Patient Age/Performance Status and Other Factors Affect This Decision?

- Multidisciplinary review
  - Surgical oncology, medical oncology, radiation oncology, radiology, gastroenterology
- Initial evaluation; systemic therapy
  - EUS/FNA/B required; ERCP/metal wallstent if jaundiced
  - Germline testing, NGS if feasible
  - (m)FOLFIRINOX or gemcitabine/nab-paclitaxel (age, performance status)
- Imaging/CA 19-9 every 4-5 cycles of therapy
- Evaluate iteratively for local therapy modality: radiation, surgery

# What is the Optimal Approach to Adjuvant Therapy: Resected PDAC? How do Patient Age/Performance Status and Other Factors Affect This Decision?

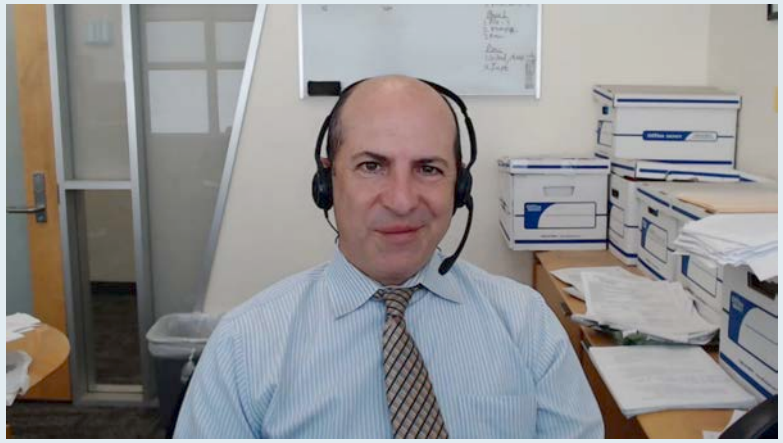
- Re-state following surgery
  - CT scan, CA 19-9/CEA
  - If CA 19-9 > 180/rising trend – likely occult M1 and treat as such
- Performance status ECOG 0-1
  - mFOLFIRINOX x 12 cycles (irinotecan 150 mg/m$^2$; reduce oxaliplatin pending neuropathy over time)
  - If R1 – consider adjuvant fluoropyrimidine-RT on completion of systemic vs observe
- Performance status ECOG ≤2
  - Gemcitabine/capecitabine (ESPAC-4) or gemcitabine alone (CONKO-001)
  - Gemcitabine/nab-paclitaxel (APACT trial OS update ASCO 2021)???

# What is your current adjuvant systemic treatment for pancreatic cancer and first-line treatment for metastatic disease?

Dr Dustin Deming

Prof Eric Van Cutsem

TikTonc



Dr Zev Wainberg

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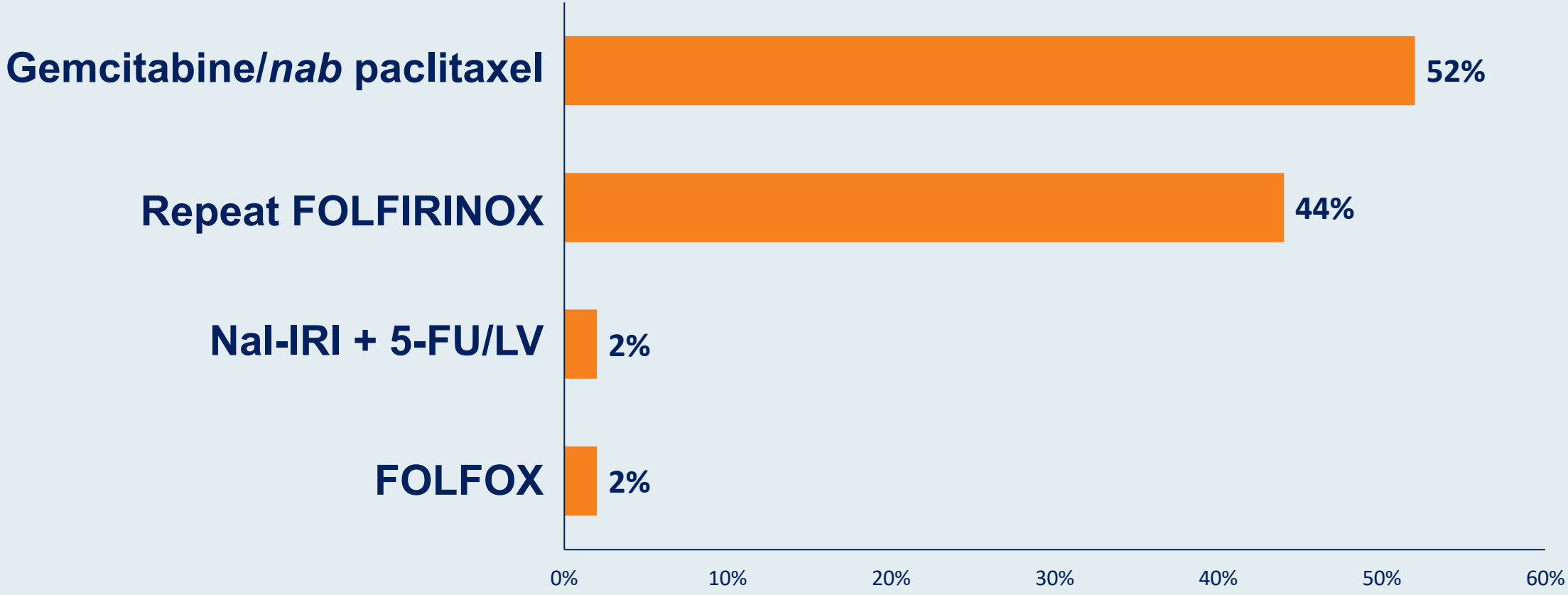
# In general, which treatment would you recommend for a patient with pancreatic cancer who developed metastatic disease 12 months after surgical resection followed by adjuvant modified FOLFIRINOX?




Premeeting survey: July 2021

RTP RESEARCH TO PRACTICE

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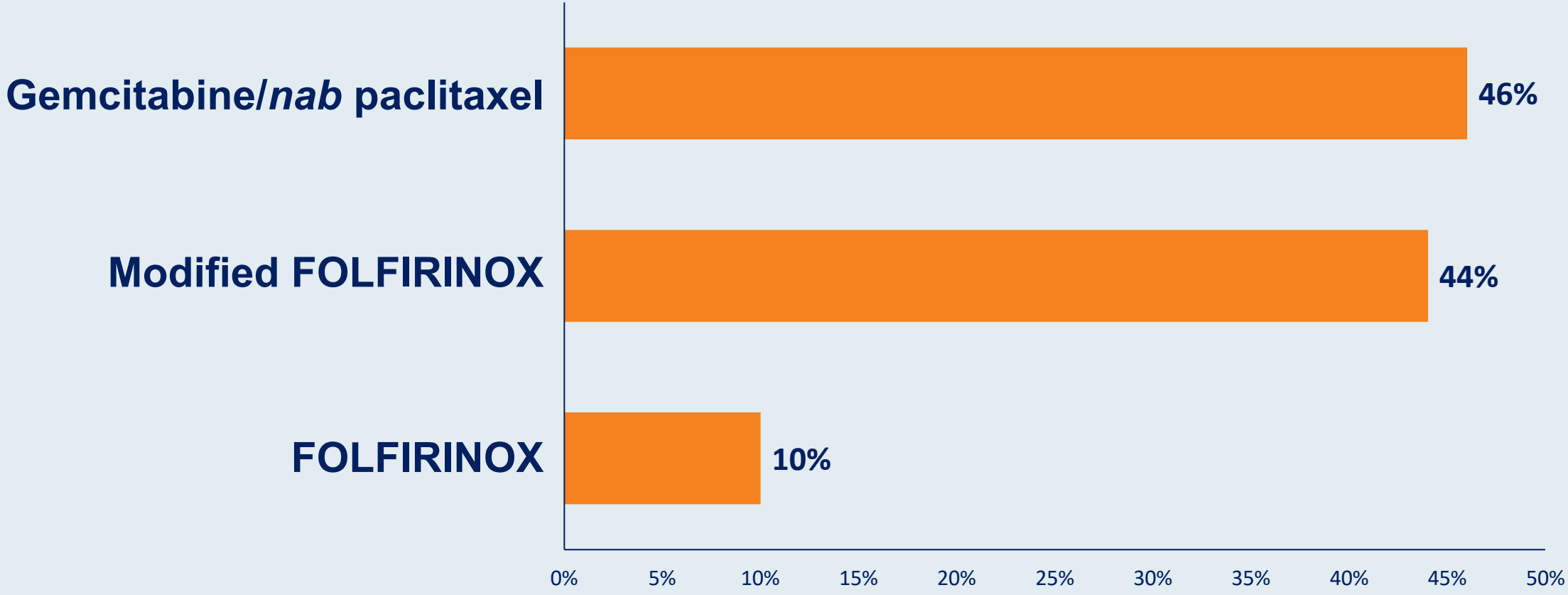
| | | | |
|---|---|---|---|
|  Dr Bekaii-Saab | Gemcitabine/*nab* paclitaxel |  Dr Atreya | Nal-IRI + 5-FU/LV |
|  Dr O'Reilly | Gemcitabine/*nab* paclitaxel |  Dr Deming | Gemcitabine/*nab* paclitaxel |
|  Dr Philip | Gemcitabine/*nab* paclitaxel |  Prof Van Cutsem | Gemcitabine/*nab* paclitaxel |
|  Dr Reiss Binder | Repeat FOLFIRINOX |  Dr Wainberg | Gemcitabine/*nab* paclitaxel |

RTP RESEARCH TO PRACTICE

# What is your usual first-line therapy recommendation for a 75-year-old patient with newly diagnosed metastatic pancreatic cancer and a PS of 0?




Premeeting survey: July 2021

RTP RESEARCH TO PRACTICE

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|  Dr Bekaii-Saab | Gemcitabine/*nab* paclitaxel |  Dr Atreya | Gemcitabine/*nab* paclitaxel |
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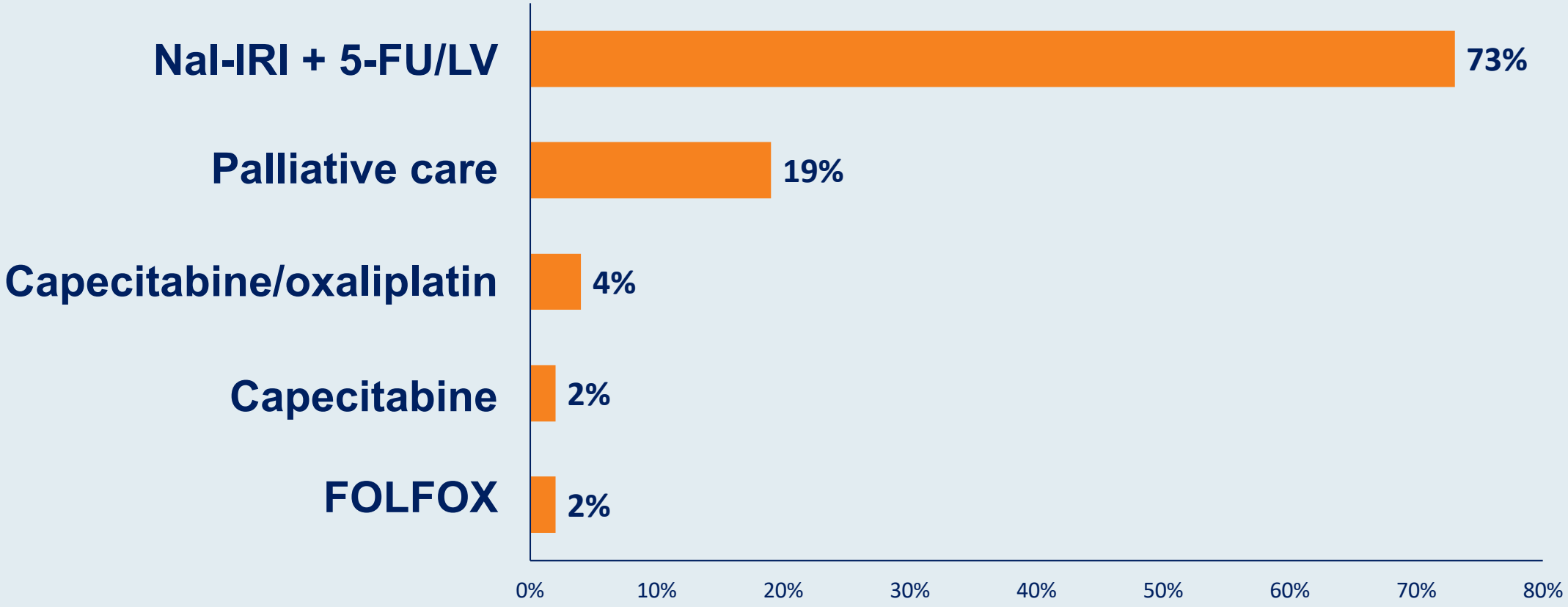
|  Dr Philip | Gemcitabine/*nab* paclitaxel |  Prof Van Cutsem | Gemcitabine/*nab* paclitaxel |
|  Dr Reiss Binder | Modified FOLFIRINOX or Gemcitabine/*nab* paclitaxel |  Dr Wainberg | Modified FOLFIRINOX |

RTP RESEARCH TO PRACTICE

# In general, which treatment would you recommend for a 65-year-old patient (PS 0) who received first-line FOLFIRINOX followed by second-line gemcitabine/*nab* paclitaxel for metastatic pancreatic cancer and experienced disease progression?




Premeeting survey: July 2021

RTP RESEARCH TO PRACTICE

# In general, which treatment would you recommend for a 65-year-old patient (PS 0) who receives first-line FOLFIRINOX followed by second-line gemcitabine/*nab* paclitaxel for metastatic pancreatic cancer and experiences disease progression?

| | | | |
|---|---|---|---|
|  Dr Bekaii-Saab | Palliative care |  Dr Atreya | Nal-IRI + 5-FU/LV |
|  Dr O'Reilly | Nal-IRI + 5-FU/LV |  Dr Deming | Nal-IRI + 5-FU/LV |
|  Dr Philip | Clinical trial |  Prof Van Cutsem | Clinical trial or BSC |
|  Dr Reiss Binder | Assuming no targetable mutations, would enroll in clinical trial if available |  Dr Wainberg | Clinical trial |

RTP RESEARCH TO PRACTICE

# How Do Factors Such As Prior Systemic Therapy, Duration Of Response, Patient Age and Presence of Comorbidities Influence Your Selection and Sequencing of Therapy for Patients with Metastatic PDAC?

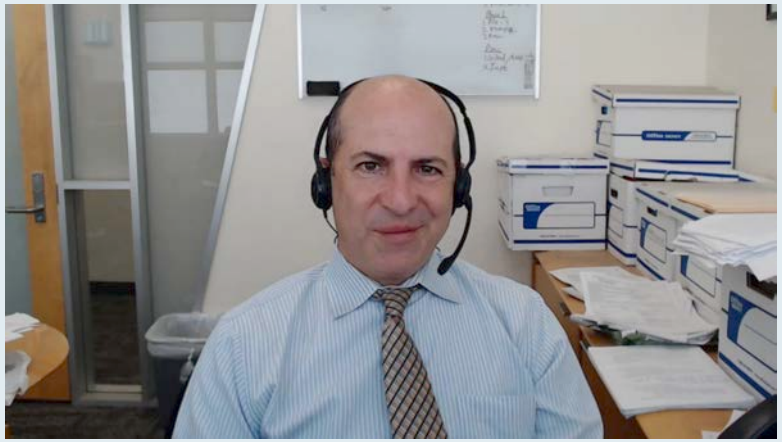
- Initial treatment for metastatic disease
  - Age, performance status, germline/somatic results (if available), major organ function, port, alopecia (patient preference)
- Performance status ECOG 0-1; Untreated
  - mFOLFIRINOX or gemcitabine/nab-paclitaxel
- Performance status ECOG ≤2; Untreated
  - Gemcitabine/nab-paclitaxel, dose-reduced; every other week
  - Gemcitabine
- Second-line therapy
  - Contingent on initial therapy; genetic results, treatment tolerance/toxicity

# In which clinical scenarios should germline and/or somatic genomic testing be done in patients with pancreatic cancer?

Dr Dustin Deming

Prof Eric Van Cutsem

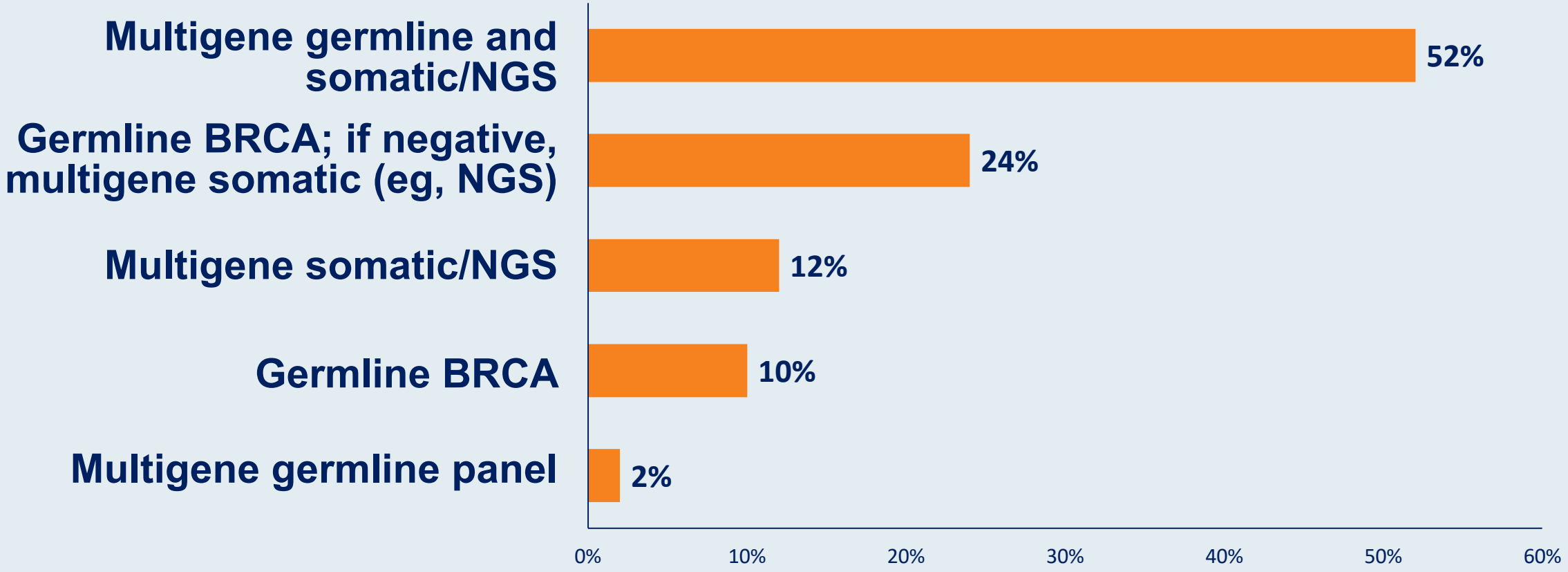
TikTonc



Dr Zev Wainberg

RTP RESEARCH TO PRACTICE

# In general, what is the optimal approach to mutation testing for possible use of a PARP inhibitor for a patient with metastatic pancreatic cancer and no family history?




Premeeting survey: July 2021

RTP RESEARCH TO PRACTICE

# In general, what is the optimal approach to mutation testing for possible use of a PARP inhibitor for a patient with metastatic pancreatic cancer and no family history?

| | |
|---|---|
|  Dr Bekaii-Saab | Multigene germline and somatic/NGS |
|  Dr O'Reilly | Multigene germline and somatic/NGS |
|  Dr Philip | Multigene germline and somatic/NGS |
|  Dr Reiss Binder | Multigene germline and somatic/NGS |
|  Dr Atreya | Multigene germline and somatic/NGS |
|  Dr Deming | Multigene germline and somatic/NGS |
|  Prof Van Cutsem | Germline BRCA |
|  Dr Wainberg | Germline BRCA |

RTP RESEARCH TO PRACTICE

Chalk Talk – Kim Reiss Binder, MD

# What's the optimal approach to mutation testing for possible PARP inhibitor use for a patient with metastatic pancreatic cancer and no FH? When should genetic testing be performed?

- ALL PATIENTS WITH mPDAC SHOULD GET GERMLINE AND SOMATIC TESTING

- Germline testing should be performed ASAP!

  *Known variant -> don't test

  *Prior testing limited and/or >5yo old -> test

  *Pick a PDAC panel! (inc. BRCA1, BRCA2, PALB2, STK11, CDKN2A, TP53, ATM, RAD51C, RAD51D, CHEK2, RAD50, NBN, ATR, FANCC, BRIP1 etc)

- Somatic testing

  *Tissue sometimes inadequate (eg FNA) -> liquid biopsy w/ ctDNA

  *If only somatic testing was done and a BRCA or other HRD variant -> germline!

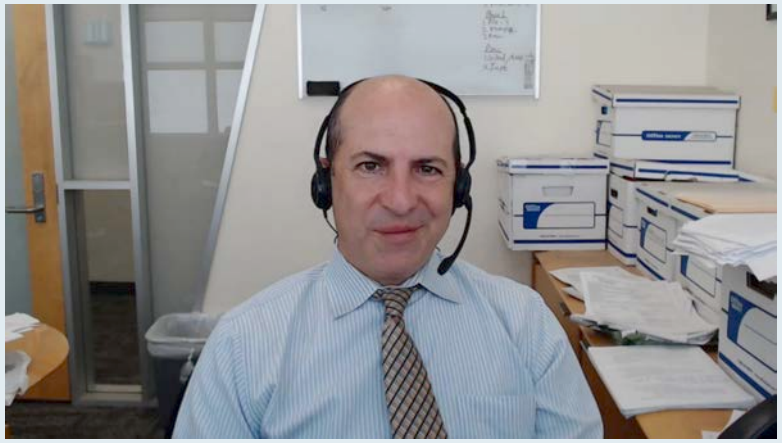
  *Role for PARPi in sBRCA: data is limited, but would consider using based on Shroff et al and Reiss et al data showing activity in these subsets

# What is the current and future role of PARP inhibitors in the treatment of pancreatic cancer?

Dr Dustin Deming

Prof Eric Van Cutsem

TikTonc



Dr Zev Wainberg

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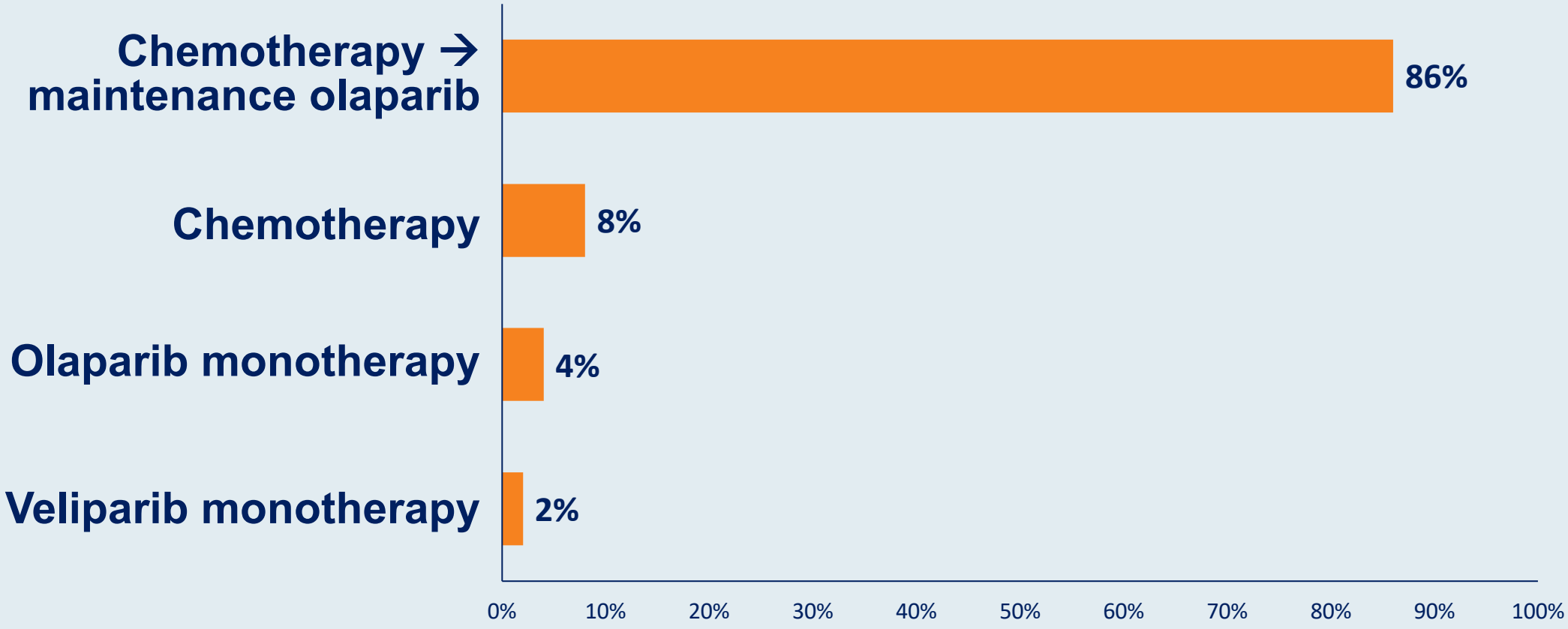
TO PRACTICE

# What is your usual first-line therapy recommendation for a 65-year-old patient with newly diagnosed metastatic pancreatic cancer and a germline BRCA mutation?




Premeeting survey: July 2021

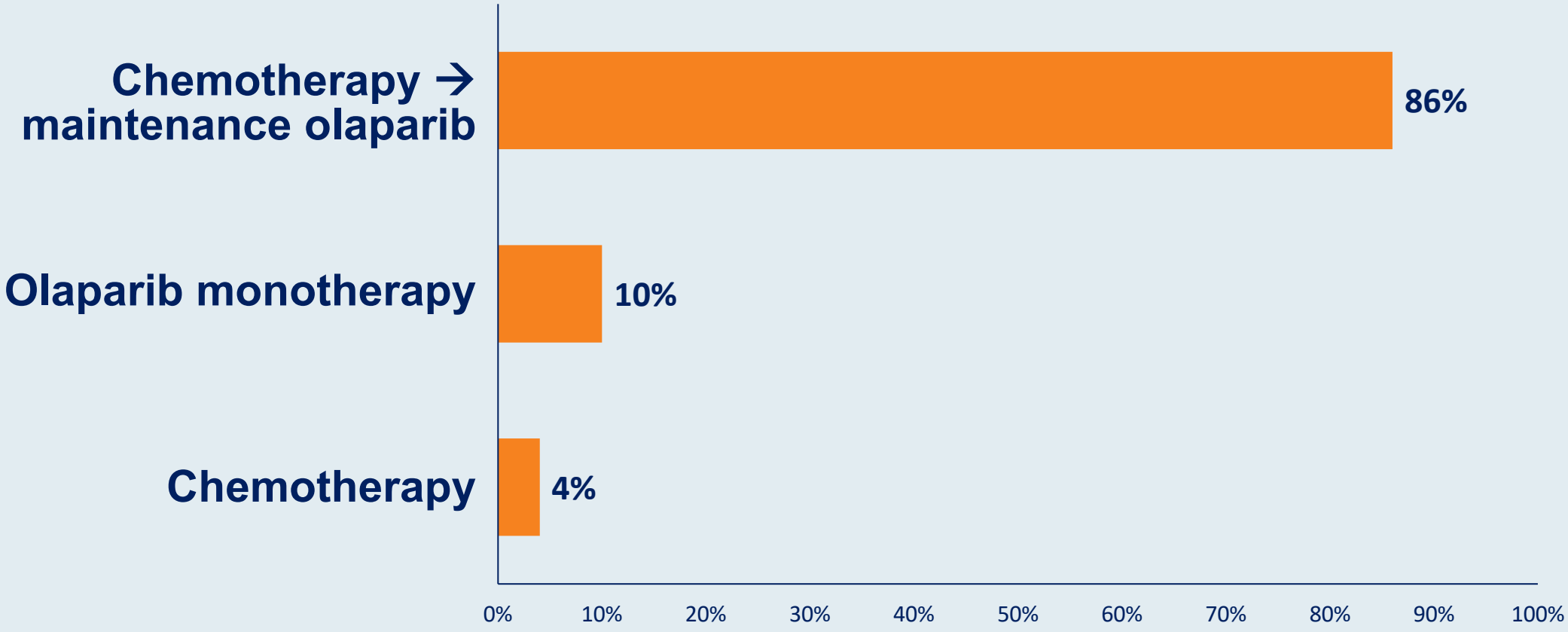
RTP RESEARCH TO PRACTICE

# What is your usual first-line therapy recommendation for a 65-year-old patient with newly diagnosed metastatic pancreatic cancer and a germline BRCA mutation?

| | |
|---|---|
|  Dr Bekaii-Saab | Gemcitabine/cisplatin |
|  Dr Atreya | mFOLFIRINOX → olaparib or rucaparib |
|  Dr O'Reilly | mFOLFIRINOX or cisplatin/gemcitabine → olaparib |
|  Dr Deming | FOLFIRINOX → PARP inhibitor |
|  Dr Philip | mFOLFIRINOX → olaparib |
|  Prof Van Cutsem | FOLFIRINOX → PARP inhibitor |
|  Dr Reiss Binder | FOLFIRINOX or cisplatin/gemcitabine → olaparib |
|  Dr Wainberg | Cisplatin/gemcitabine → PARP inhibitor |

RTP RESEARCH TO PRACTICE

# What is your usual first-line therapy recommendation for a 78-year-old patient with newly diagnosed metastatic pancreatic cancer and a germline BRCA mutation?




Premeeting survey: July 2021

RTP RESEARCH TO PRACTICE

# What is your usual first-line therapy recommendation for a 78-year-old patient with newly diagnosed metastatic pancreatic cancer and a germline BRCA mutation?

| | | | |
|---|---|---|---|
|  Dr Bekaii-Saab | Cisplatin/gemcitabine |  Dr Atreya | Cisplatin/gemcitabine → olaparib or rucaparib |
|  Dr O'Reilly | Cisplatin/gemcitabine → olaparib |  Dr Deming | mFOLFIRINOX or cisplatin/gemcitabine or FOLFOX → PARP inhibitor |
|  Dr Philip | Cisplatin/gemcitabine → olaparib |  Prof Van Cutsem | FOLFOX or cisplatin/gemcitabine → PARP inhibitor |
|  Dr Reiss Binder | Cisplatin/gemcitabine → olaparib |  Dr Wainberg | Cisplatin/gemcitabine → PARP inhibitor |

RTP RESEARCH TO PRACTICE

# What is the optimal first line therapy for a patient with newly diagnosed mPDAC and gBRCA mutation, and how do patient age/PS etc affect this decision? Should all patients with mPDAC and gBRCA be offered maintenance with olaparib if no PD on first-line chemotherapy?

- All patients with known gBRCA mutations should get a **platinum therapy** in the front line setting
- Reasonable options:
  - mFOLFIRINOX, Cis/Gem — Preferred based on prospective data
  - FOLFOX, Gem/Ox — Also reasonable if comorbidities prevent the above
- Barriers to giving mFOLFIRINOX or cis/gem:

  -Poor PS + renal dysfunction and/or hearing loss
- Maintenance olaparib is an option -> Joint patient/physician decision based on chemo toxicity, patient wishes

  -Early olaparib maintenance (<4mo chemo); maintenance FOLFIRI; maintenance 5FU

# Regulatory and reimbursement issues aside, would you generally administer a PARP inhibitor to a patient with metastatic pancreatic cancer and a DDR abnormality beyond germline BRCA at some point?

| | | | |
|---|---|---|---|
|  Dr Bekaii-Saab | No |  Dr Atreya | Yes |
|  Dr O'Reilly | Yes |  Dr Deming | No |
|  Dr Philip | No |  Prof Van Cutsem | Yes |
|  Dr Reiss Binder | Yes |  Dr Wainberg | Yes |

RTP RESEARCH TO PRACTICE

**Chalk Talk – Kim Reiss Binder, MD**

# Regulatory and reimbursement issues aside, should patients with mPDAC and DDR abnormalities beyond gBRCA who do not experience PD on first line chemotherapy be offered olaparib maintenance? If so, which ones?

- Would consider PARPi maintenance in gPALB2 and sBRCA based on small but consistent clinical trial data

- Would NOT consider for ATM carriers -> PARPi monotherapy Ø impressive

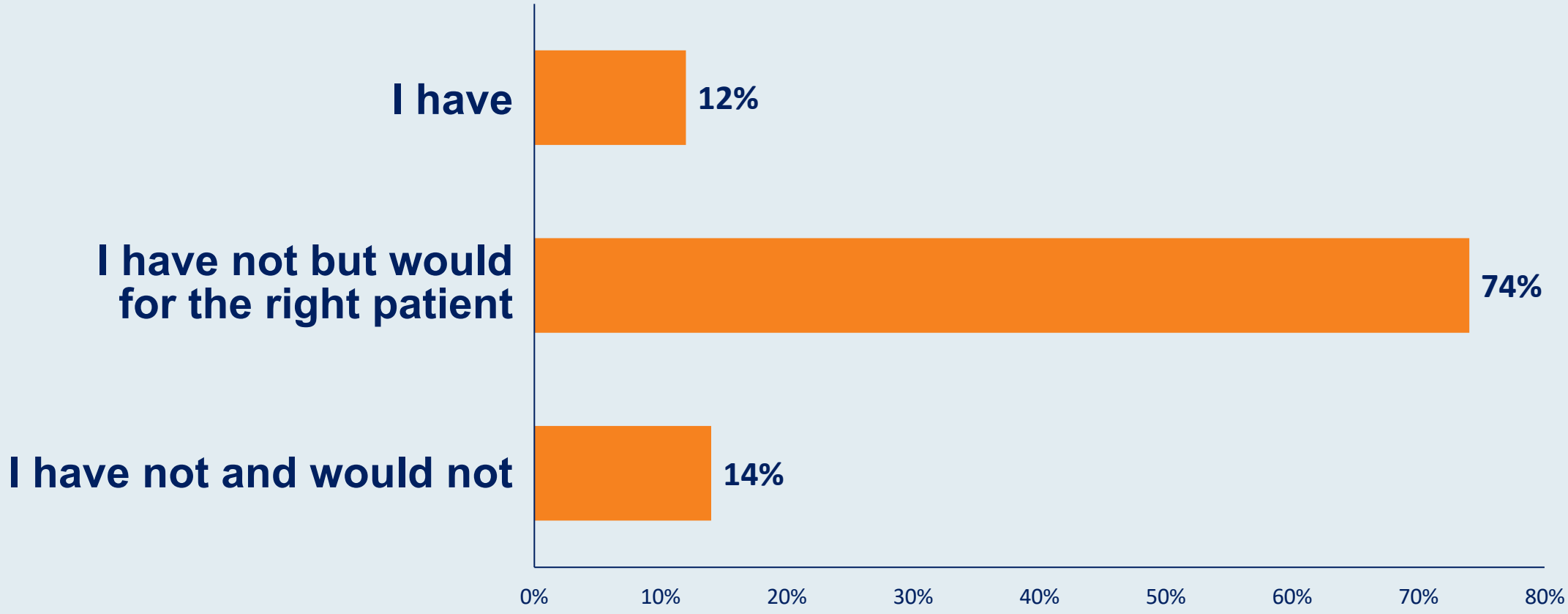
- Data for PARPi maintenance monotherapy in other DDR abnormalities is not mature...

  -Genomic variant identification is insufficient to predict PARPi efficacy

  -We need clinically usable biomarkers to predict PARPi sensitivity

  -Clinical trials!!!

# Have you administered or would you administer olaparib monotherapy to a patient with metastatic pancreatic cancer who could not tolerate or did not wish to receive chemotherapy?

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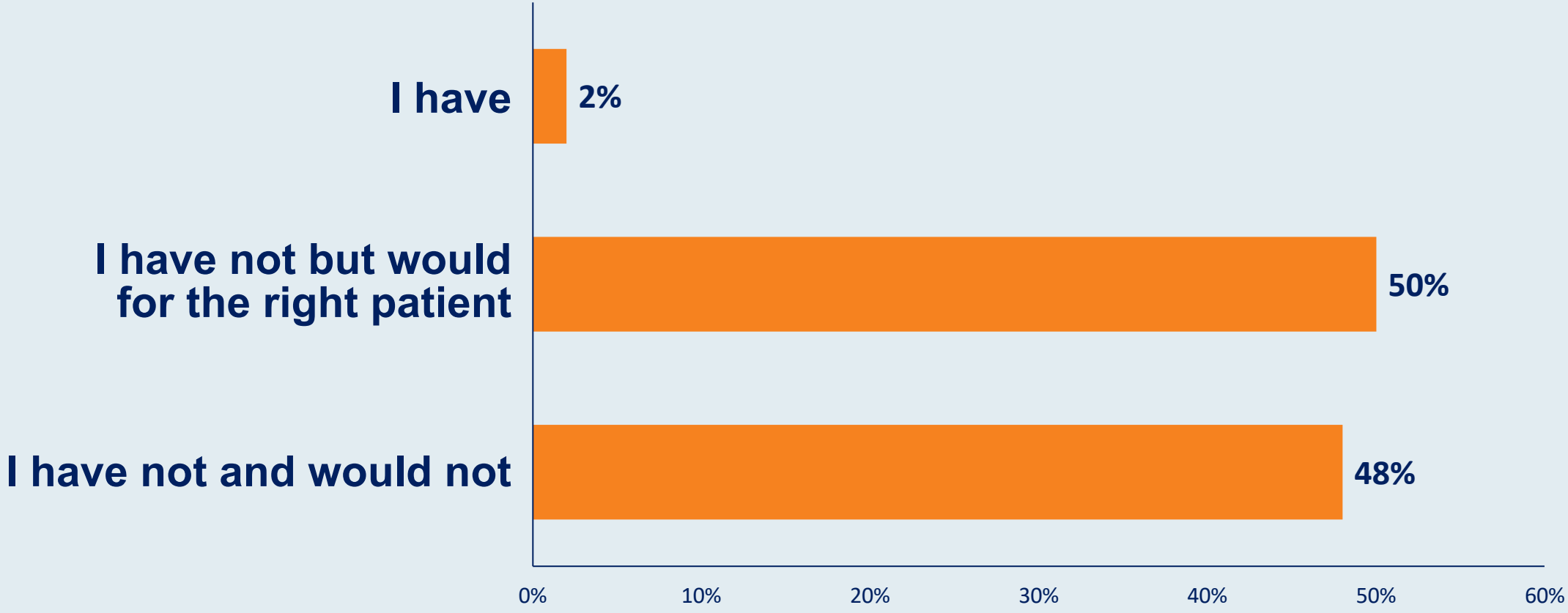
RTP RESEARCH TO PRACTICE

# Have you or would you administer olaparib monotherapy to a patient with metastatic pancreatic cancer who could not tolerate or did not wish to receive chemotherapy?

| | | | |
|---|---|---|---|
|  Dr Bekaii-Saab | I have (not preferred) |  Dr Atreya | I have not but would for the right patient |
|  Dr O'Reilly | I have |  Dr Deming | I have not and would not |
|  Dr Philip | I have not but would for the right patient |  Prof Van Cutsem | I have not but would for the right patient |
|  Dr Reiss Binder | I have not but would for the right patient |  Dr Wainberg | I have |

RTP RESEARCH TO PRACTICE

# Outside of a clinical trial, have you administered or would you administer a PARP inhibitor as a component of neoadjuvant or adjuvant therapy to a patient with pancreatic cancer and a germline BRCA mutation?




Premeeting survey: July 2021

RTP RESEARCH TO PRACTICE

# Outside of a clinical trial, have you or would you administer a PARP inhibitor as a component of neoadjuvant or adjuvant therapy to a patient with pancreatic cancer and a germline BRCA mutation?

| | | | |
|---|---|---|---|
|  Dr Bekaii-Saab | I have not and would not |  Dr Atreya | I have not and would not |
|  Dr O'Reilly | I have |  Dr Deming | I have not and would not |
|  Dr Philip | I have not but would for the right patient |  Prof Van Cutsem | I have not and would not |
|  Dr Reiss Binder | I have not and would not |  Dr Wainberg | I have not and would not |

RTP RESEARCH TO PRACTICE

# Questions for the Faculty from Webinar Registrants – Pancreatic Cancer

- **Germline vs somatic testing in patients with pancreatic cancer?**
- **Is liquid biopsy useful in pancreatic cancer?**
- **Do you use PARP inhibitor for mutations other than BRCA?**
- **Is there a role of PARPi as a first line therapy either as single agent or in combination with chemotherapy?**
- **Would you use olaparib as first-line therapy in a PS2 patient who cannot tolerate chemotherapy?**
- **Which PARPi is best?**
- **Use of adjuvant PARP inhibitors in germline BRCA positive pancreatic cancer**
- **Neoadjuvant olaparib is very interesting in breast cancer. Any data in pancreatic?**

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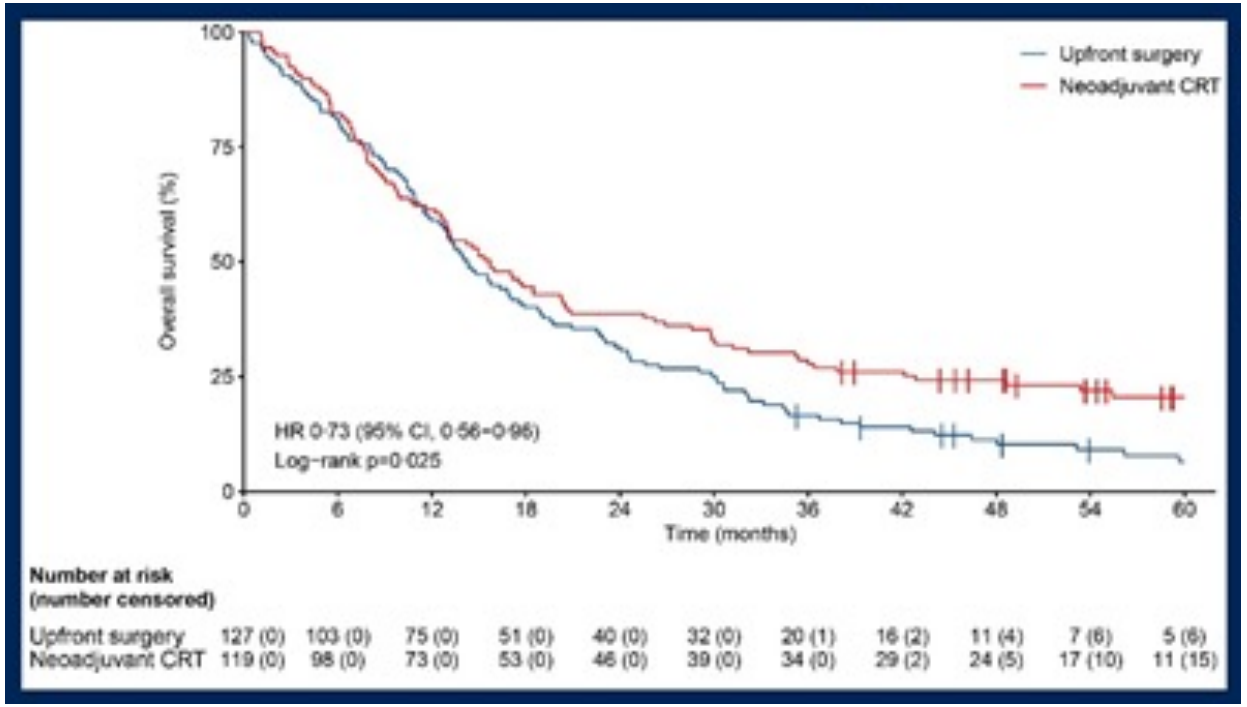
RTP RESEARCH TO PRACTICE

# Long-term PREOPANC: Updated ASCO 2021




HR 0.73 (0.56-0.96) Log-rank p= 0.025

| | Median OS | 5-Year OS |
|---|---|---|
| Neoadjuvant CRT | 15.7 mo | 20.5% |
| Upfront Surgery | 14.3 mo | 6.5% |

van Eijck, C, et al. Proc ASCO, 2021 [Abstr 4016]

Courtesy of Eileen M O'Reilly, MD

Memorial Sloan Kettering Cancer Center

# S1505: Perioperative Trial Results (Resectable)

| | mFOLFIRINOX N= 55 | Gem/Nab-Paclitaxel N= 47 | P-Value |
|---|---|---|---|
| Surgical Resection | 40 (73%) | 33 (70%) | |
| CR/Major Path response | 10 (25%) | 14 (42%) | |
| Completed All Therapy | 27 (49%) | 19 (40%) | |
| Two Year OS | 41.6% | 48.8% | NS |
| Median OS | 22.4 m | 23.6 m | |
| Median DFS after Surgery | 10.9 m | 14.2 m | p= 0.87 |

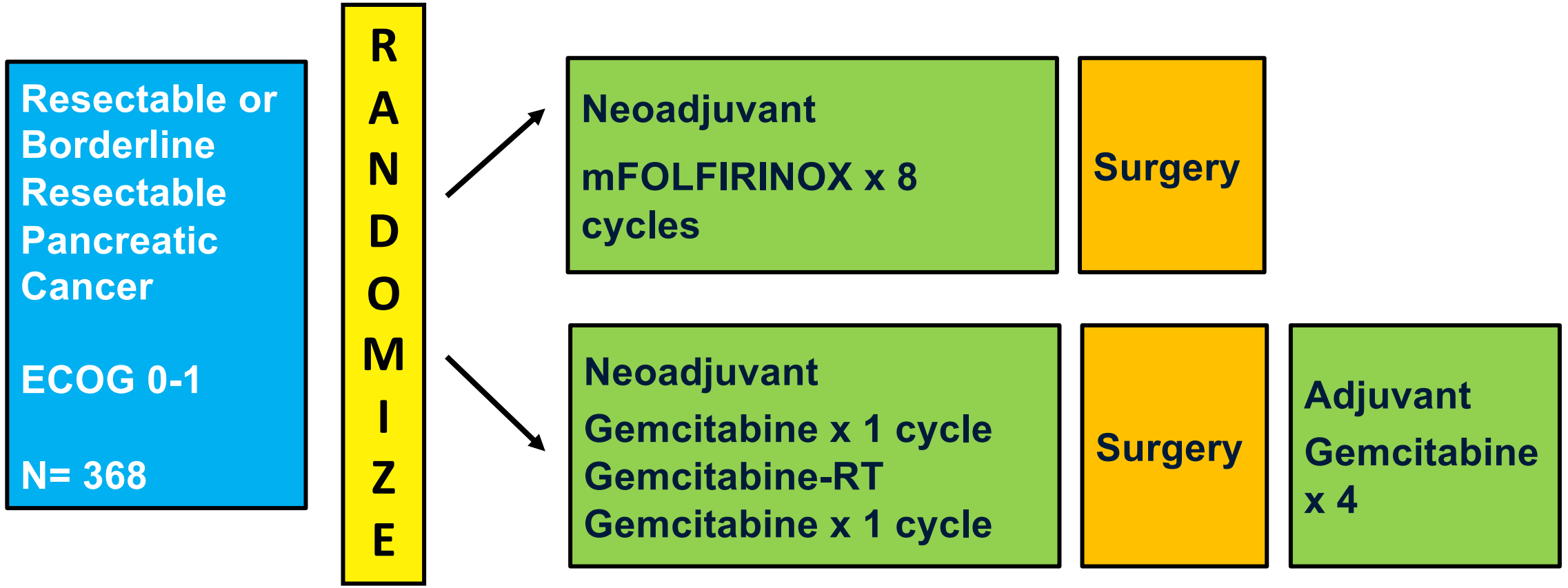
Sohal, D, et al. JAMA Oncology, 2021

Courtesy of Eileen M O'Reilly, MD

Memorial Sloan Kettering Cancer Center

# PREOPANC-2: Resectable/Borderline

## Completed Recruitment 2021 and Results Pending




Primary endpoint: Overall survival

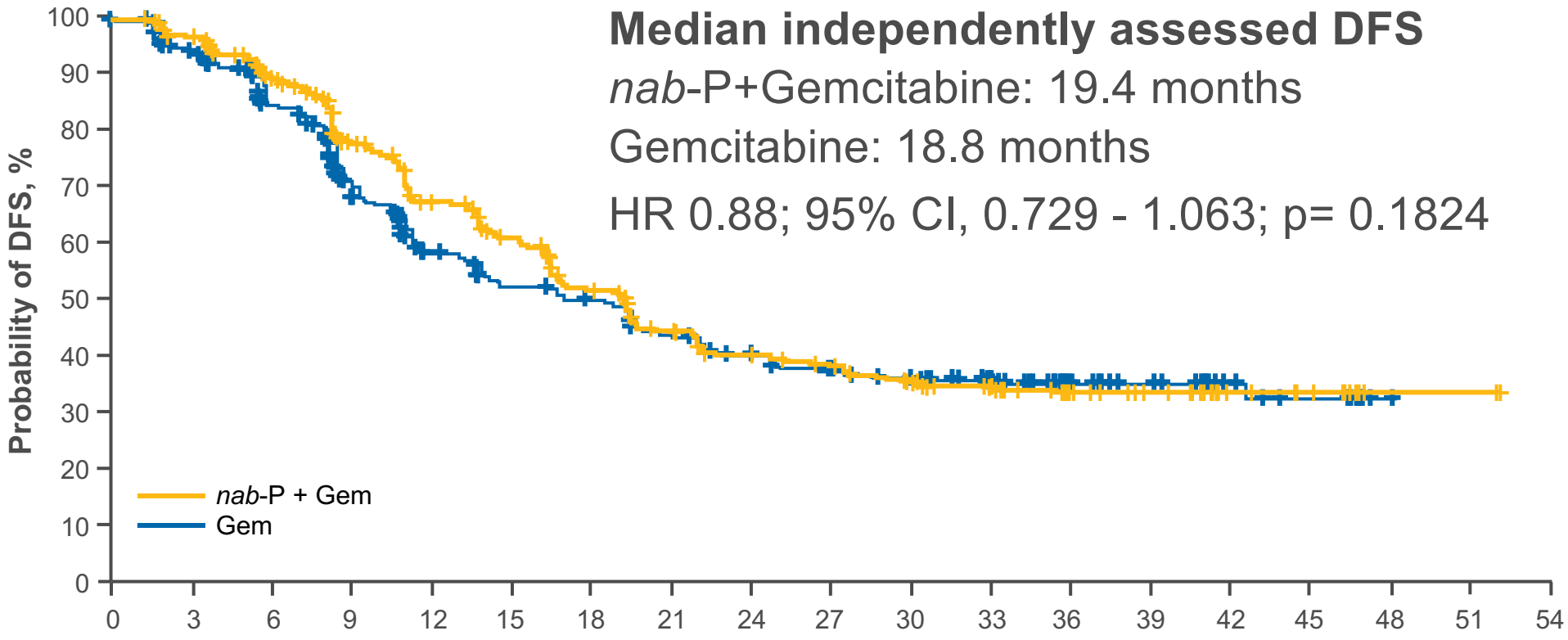
Stratify: Resectability, Institution

NL7094 Dutch Pancreatic Cancer Group

Courtesy of Eileen M O'Reilly, MD

Memorial Sloan Kettering Cancer Center

# APACT – Primary Endpoint: Independently Assessed DFS (ITT)




**Median independently assessed DFS**

*nab*-P+Gemcitabine: 19.4 months

Gemcitabine: 18.8 months

HR 0.88; 95% CI, 0.729 - 1.063; p= 0.1824

**Patients at risk**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| *nab*-P + Gem | 432 | 391 | 338 | 279 | 236 | 204 | 167 | 138 | 121 | 112 | 99 | 88 | 54 | 43 | 20 | 14 | 2 | 2 |
| Gem | 434 | 368 | 309 | 235 | 183 | 157 | 147 | 127 | 116 | 105 | 98 | 88 | 59 | 42 | 15 | 10 | 1 | |

Tempero, M. J Clin Oncol. 2019;37(suppl): Abstract LBA4000

Courtesy of Eileen M O'Reilly, MD

Memorial Sloan Kettering Cancer Center

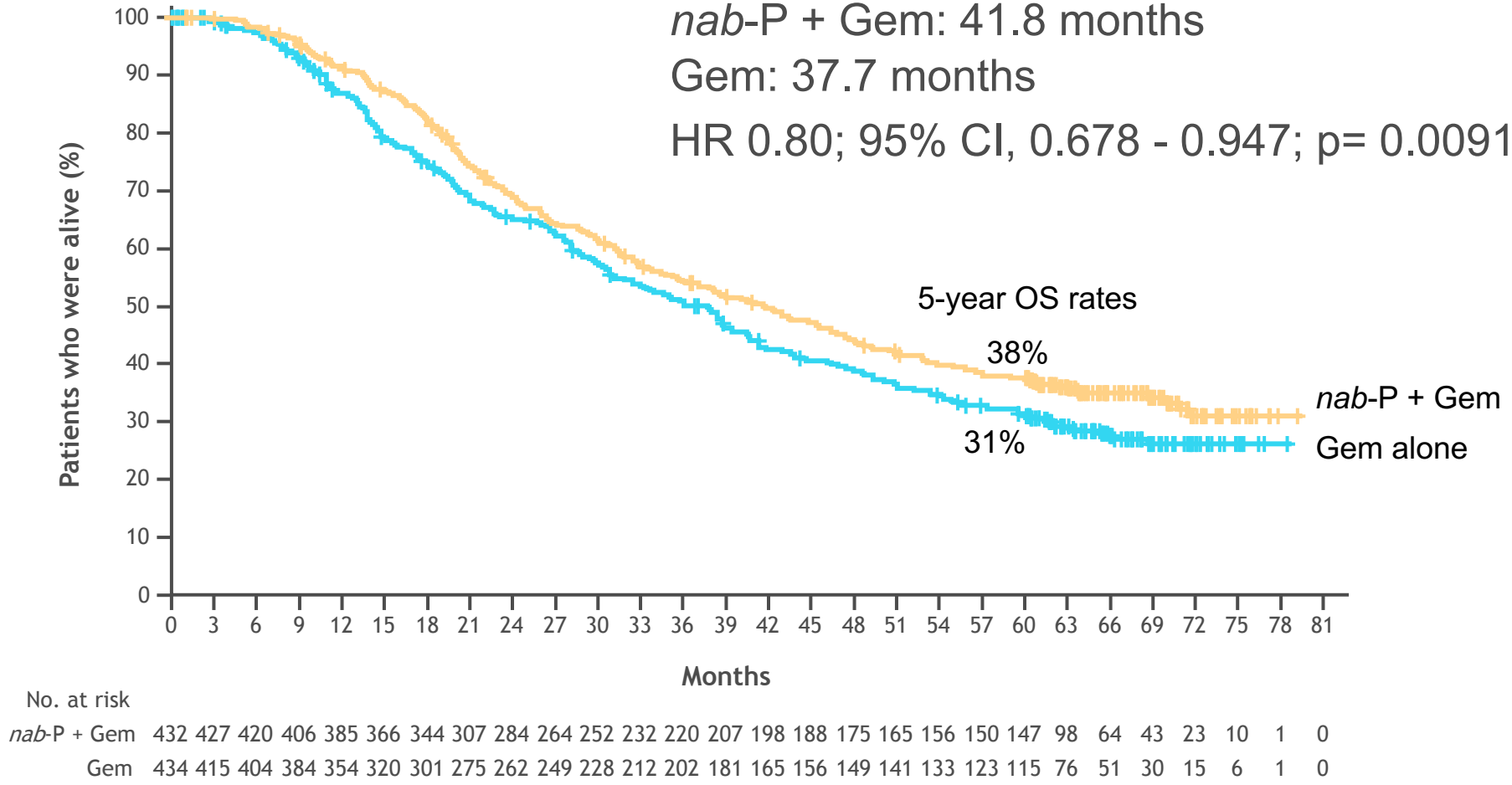
# APACT – Secondary Endpoint: 5-Year OS (Updated 2021)

**Five Year OS (median follow-up 63 months)**

*nab*-P + Gem: 41.8 months

Gem: 37.7 months

HR 0.80; 95% CI, 0.678 - 0.947; p= 0.0091




No. at risk

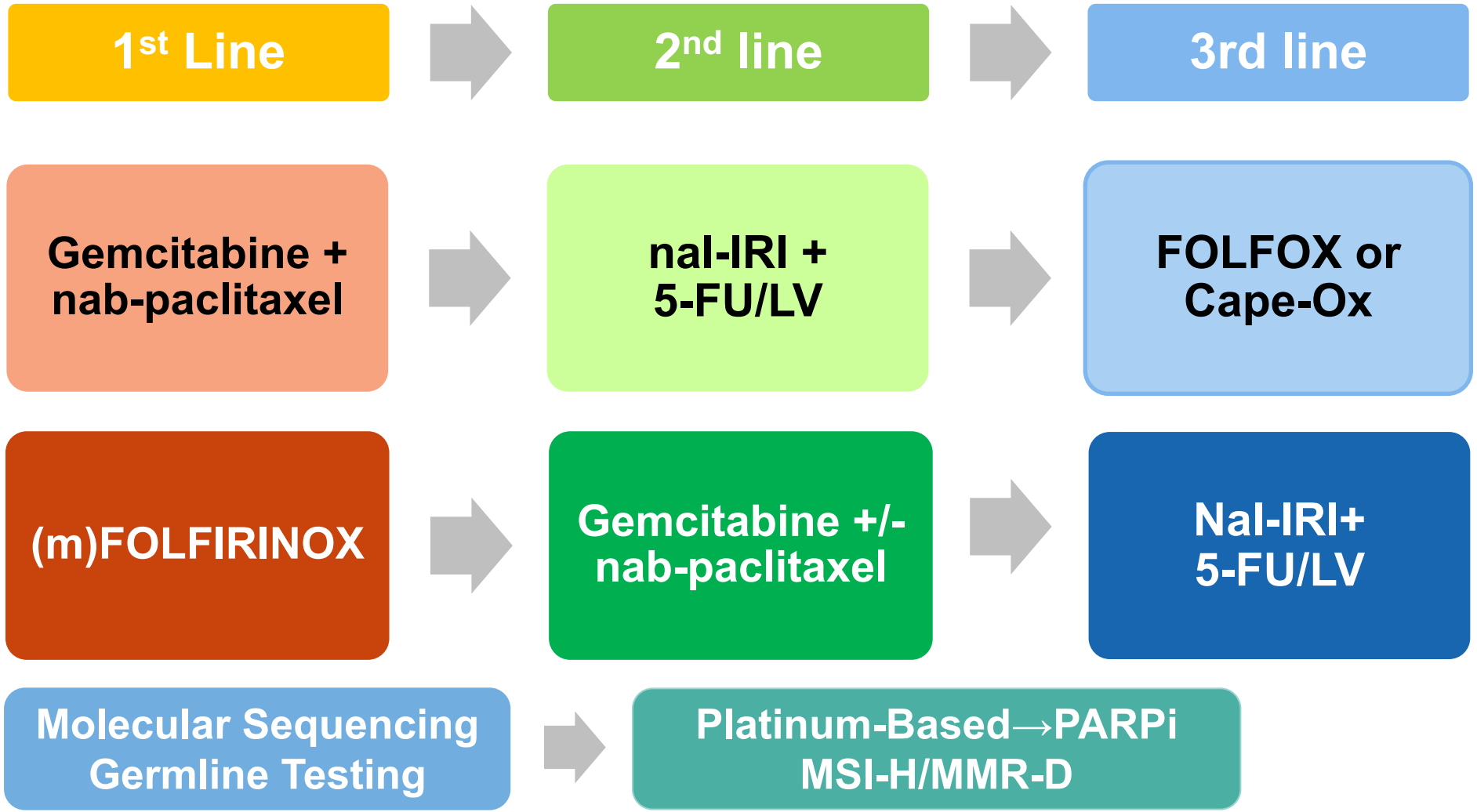
| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| *nab*-P + Gem | 432 | 427 | 420 | 406 | 385 | 366 | 344 | 307 | 284 | 264 | 252 | 232 | 220 | 207 | 198 | 188 | 175 | 165 | 156 | 150 | 147 | 98 | 64 | 43 | 23 | 10 | 1 | 0 |
| Gem | 434 | 415 | 404 | 384 | 354 | 320 | 301 | 275 | 262 | 249 | 228 | 212 | 202 | 181 | 165 | 156 | 149 | 141 | 133 | 123 | 115 | 76 | 51 | 30 | 15 | 6 | 1 | 0 |

Tempero, M, et al. ESMO World GI, 2021

Courtesy of Eileen M O'Reilly, MD

Memorial Sloan Kettering Cancer Center

# Sequencing Therapy in Advanced PDAC




Courtesy of Eileen M O'Reilly, MD

Memorial Sloan Kettering Cancer Center

# Optimal Strategy for Genetic Testing in Clinical Practice

- **All patients with a diagnosis of PDAC should be offered germline genetic testing, regardless of stage**
- **If a patient declines testing or dies prior to having testing, first degree relatives of that patient should be offered genetic testing**

- **There are multiple available platforms that provide adequate testing**
  - -Do not limit to just *BRCA* variants. Ideal testing includes a panel of genes that specifically increase risk for pancreatic cancer. Examples include: PancNext, Pancreatic Cancer Panel, MyRisk
  - -If a patient previously had limited testing (e.g. *BRCA* testing for breast cancer), reasonable to retest
  - -Clinical trial: "eREACH" aiming to provide testing and telemedicine genetic counseling across the US

- **Positive tests may have implications for treatment for patients at every stage**
  - -Platinum based chemotherapy should be used in those with *BRCA* or *PALB2* variants[1]
  - -Olaparib maintenance option in the advanced disease setting[2]
  - -Clinical trial options for those with specific variants, including an ongoing trial of olaparib as adjuvant treatment after curative intent therapy

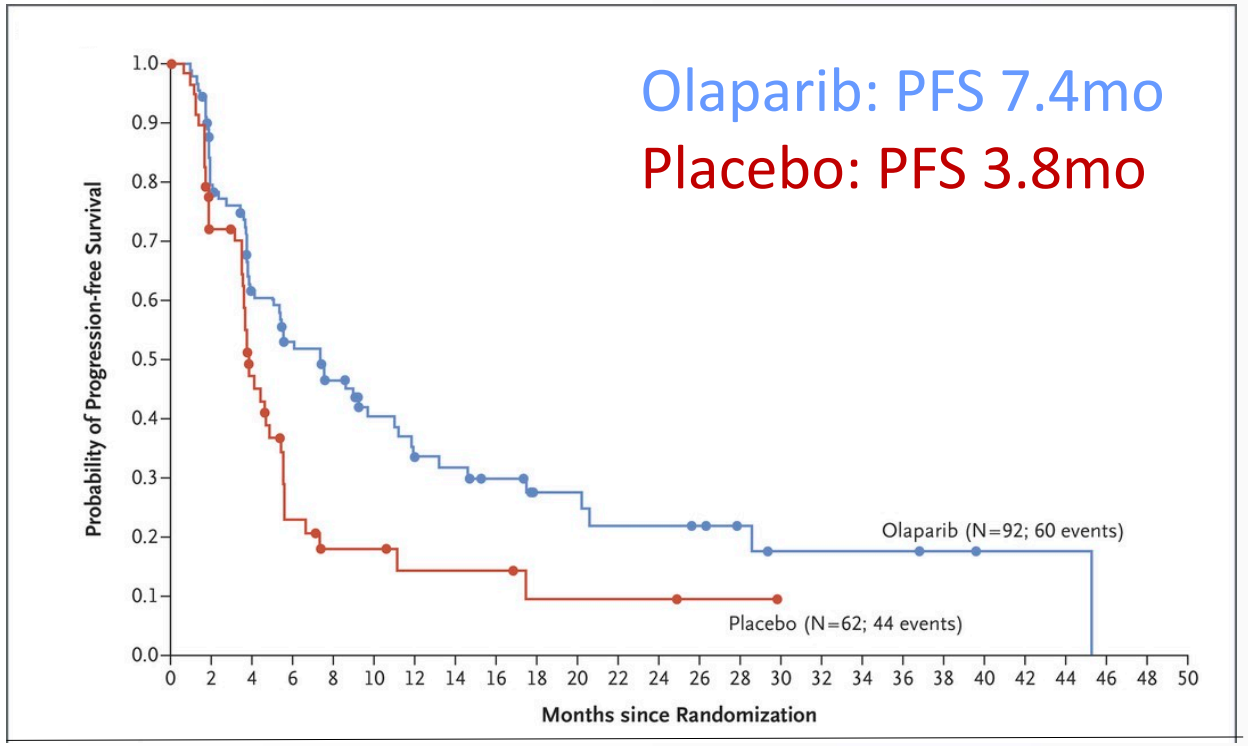
[1]O'Reilly et al, JCO, 2020; Golan et al, NEJM, 2019

Courtesy of Kim A Reiss Binder, MD

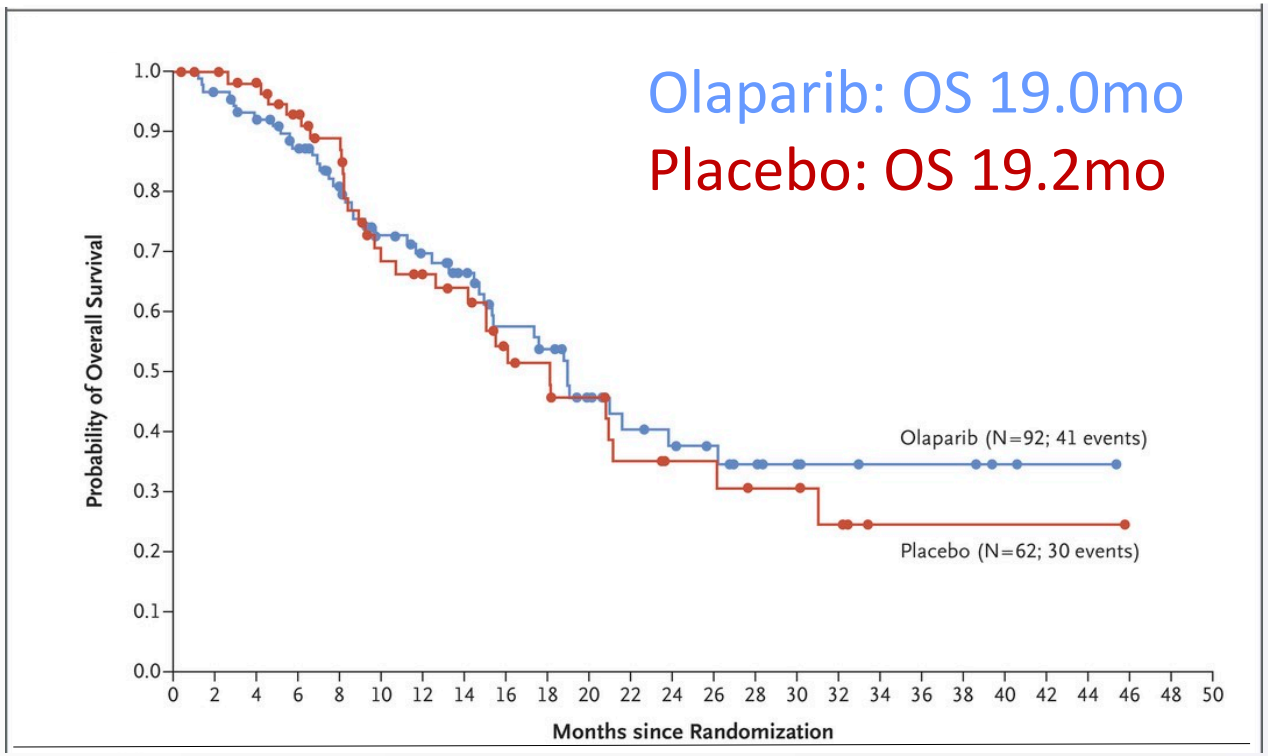
# The POLO Trial

## Key Efficacy Data

### PFS




### OS*



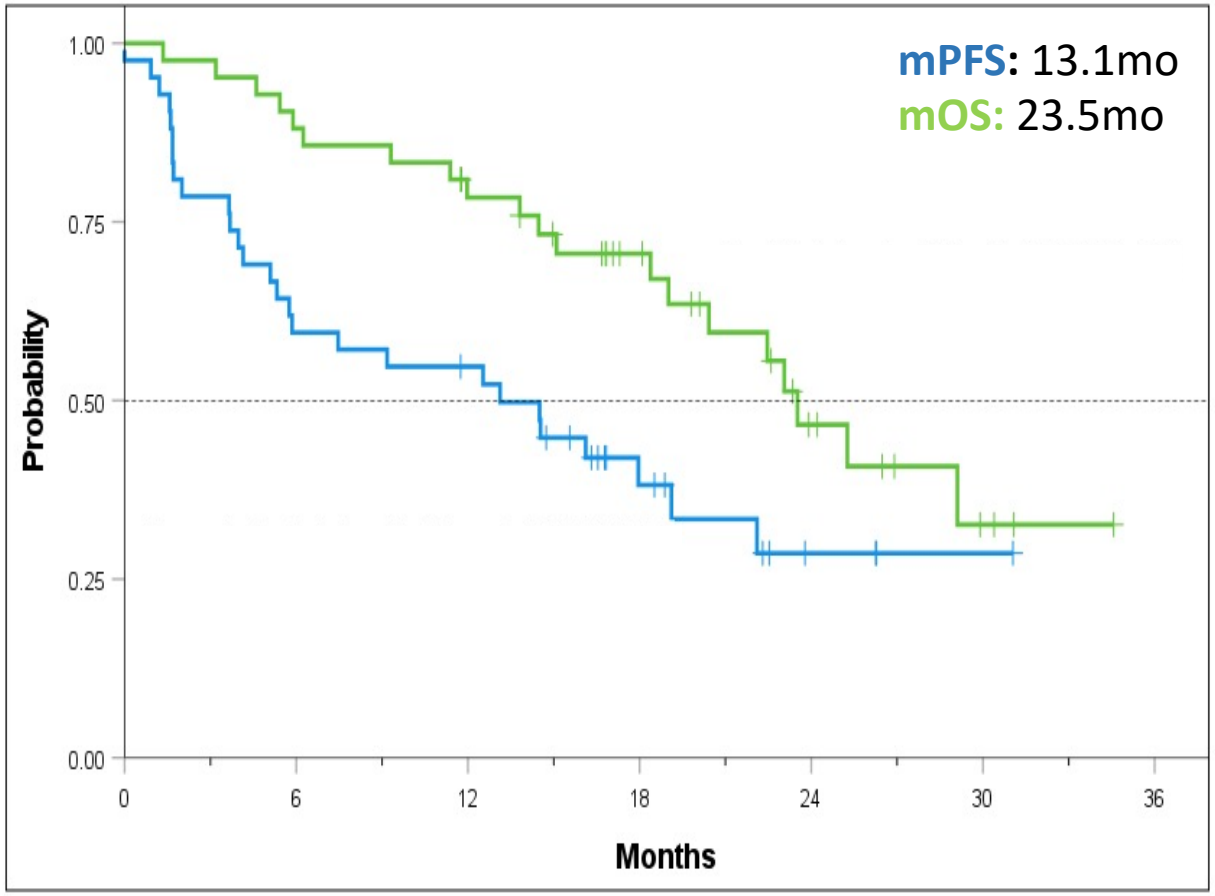

Golan et al, NEJM, 2019

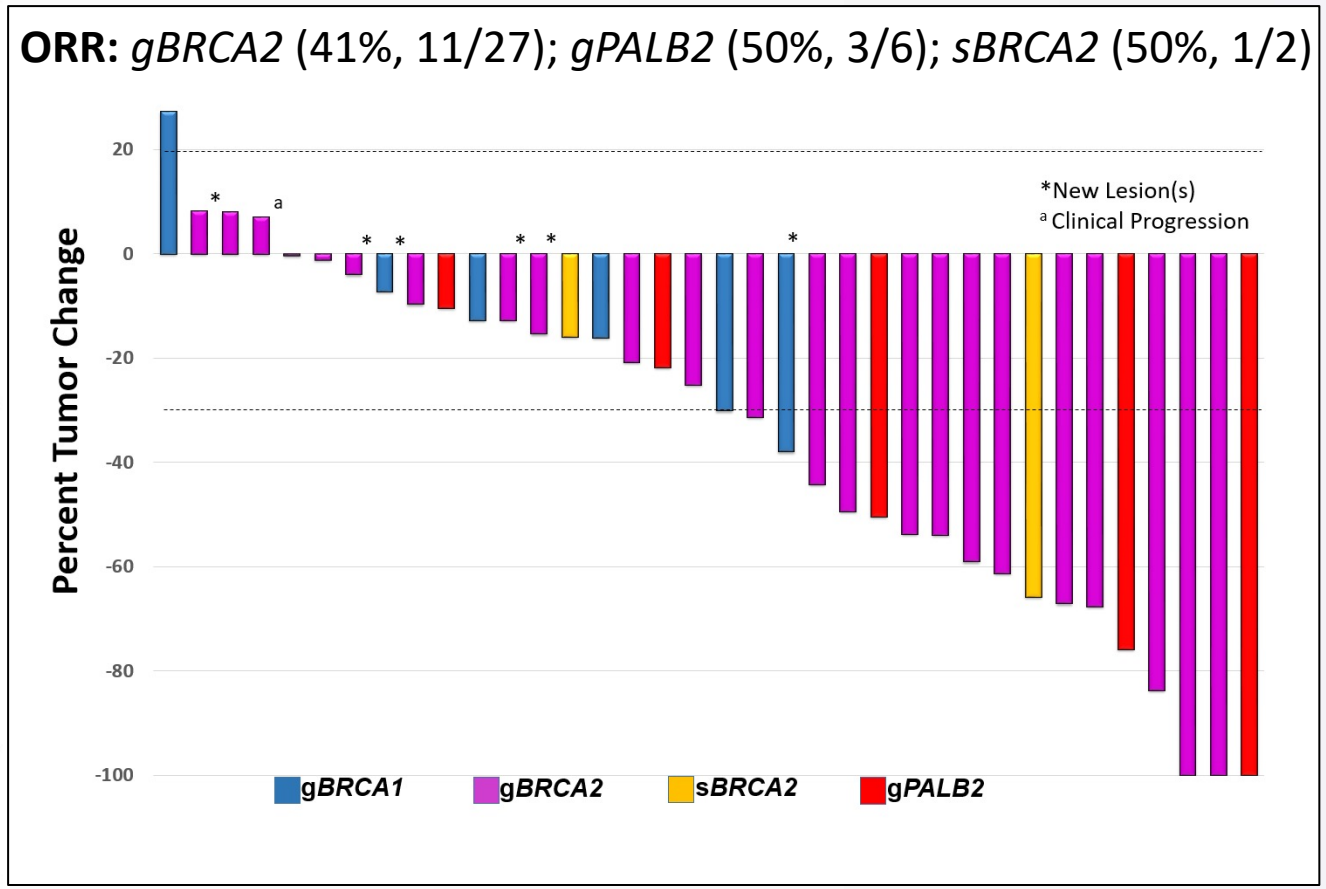
*Final OS data from ASCO GI 2021

Courtesy of Kim A Reiss Binder, MD

# Rucaparib Maintenance – Phase II Trial

## Kaplan-Meier Curve & Waterfall Plot



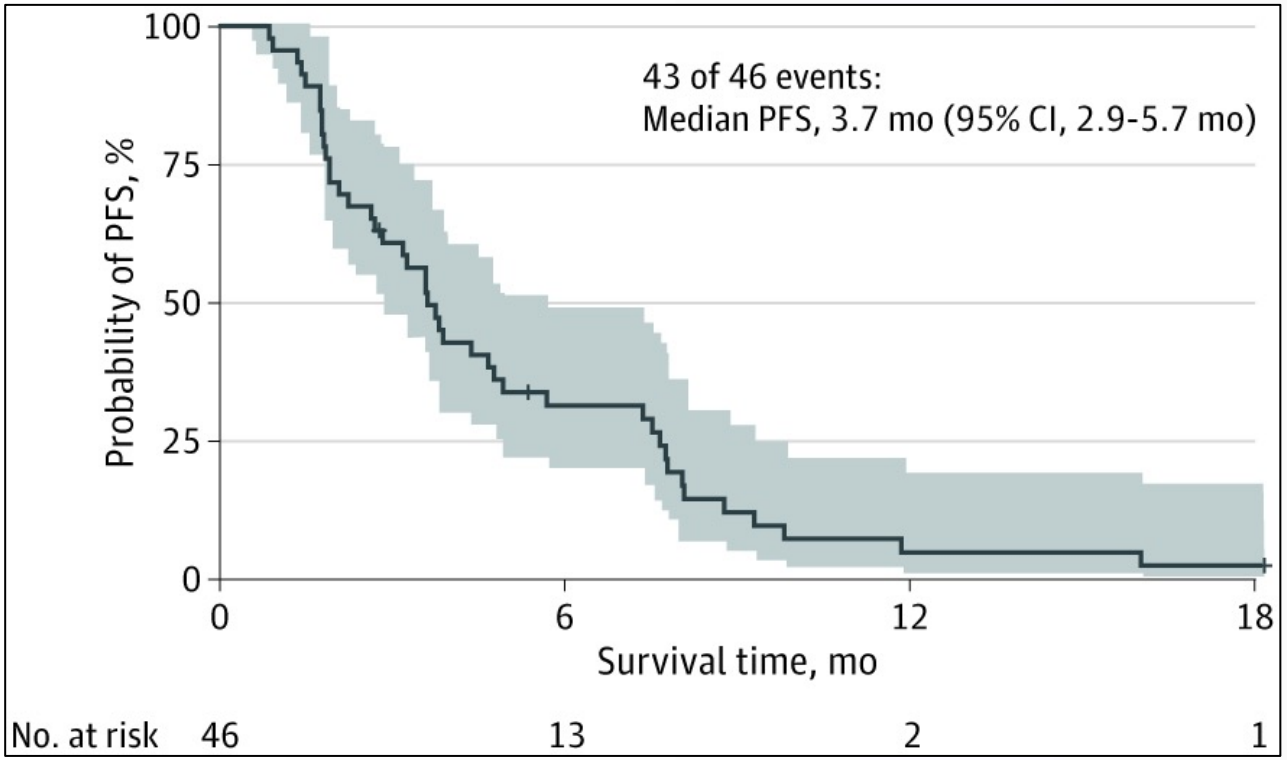

Reiss et al, JCO, 2021

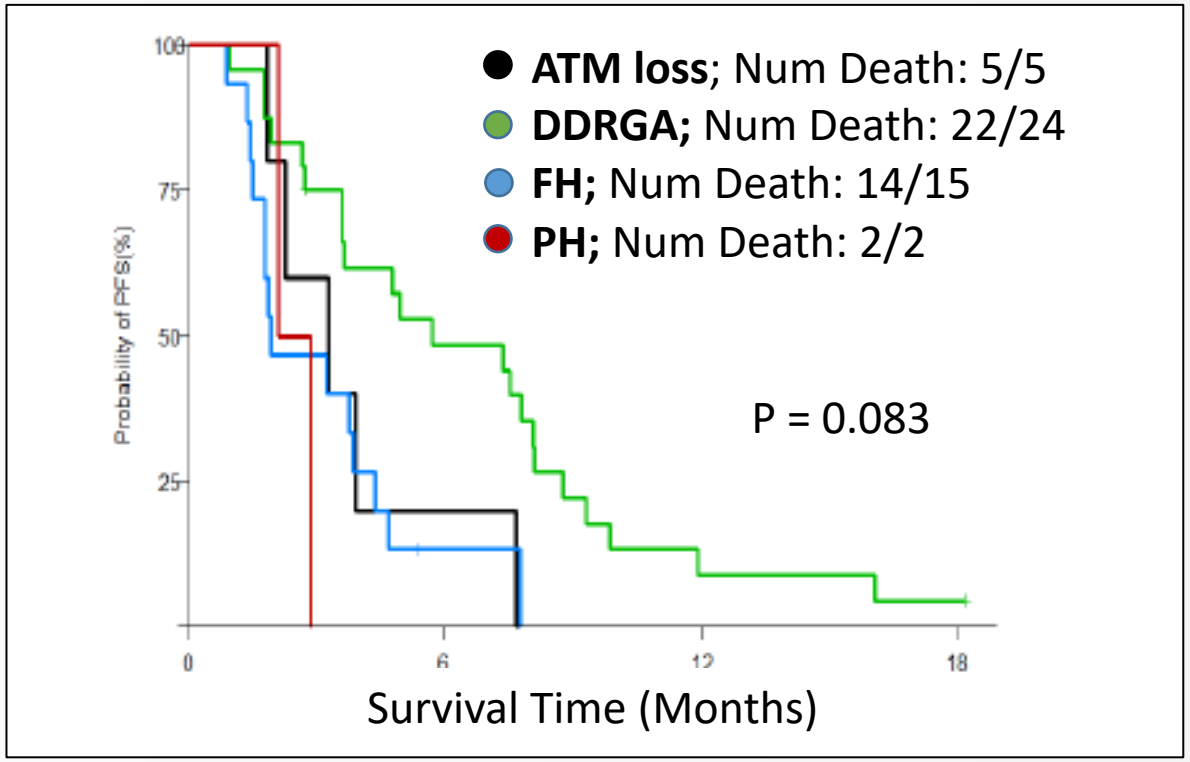
Courtesy of Kim A Reiss Binder, MD

# Olaparib for Previously Treated PDAC with DDR Variants or +FH

## Phase II Trial Results

- **mPFS 3.7mo (comparable to second- and third-line chemotherapy)**
- **Best outcomes in those with DDR-GA's and those with platinum-sensitive disease; little activity in +FH patients without identified GA**




Javle et al, JAMA Oncology, 2021

Courtesy of Kim A Reiss Binder, MD

# Agenda

## Interdisciplinary Care: Supportive, Palliative and Complementary Strategies – Part 1

## Module 1: Hepatocellular Carcinoma (HCC)

- What is the optimal first-line systemic treatment for advanced HCC with Child-Pugh A and B cirrhosis?
- What is the optimal second-line systemic treatment for advanced HCC after atezolizumab/bevacizumab?

## Interdisciplinary Care: Supportive, Palliative and Complementary Strategies – Part 2

## Module 2: Pancreatic Cancer

- In what situations, if any, do you utilize neoadjuvant chemotherapy for patients with potentially resectable primary pancreatic cancer?
- What is your current adjuvant systemic treatment for pancreatic cancer and first-line treatment for metastatic disease?
- In which clinical scenarios should germline and/or somatic genomic testing be done in patients with pancreatic cancer?
- What is the current and future role of PARP inhibitors in the treatment of pancreatic cancer?

## Interdisciplinary Care: Supportive, Palliative and Complementary Strategies – Part 3

## Module 3: Cholangiocarcinoma

- What somatic and/or germline testing, if any, should be performed in cholangiocarcinoma?
- How often are FGFR2 translocations observed in cholangiocarcinoma? What are the risks and benefits of FGFR2 inhibitors?

# Agenda

## Interdisciplinary Care: Supportive, Palliative and Complementary Strategies – Part 1

## Module 1: Hepatocellular Carcinoma (HCC)

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- How often are FGFR2 translocations observed in cholangiocarcinoma? What are the risks and benefits of FGFR2 inhibitors?

RTP RESEARCH TO PRACTICE

# Questions for the Faculty from Webinar Registrants – Cholangiocarcinoma

- **Algorithm for management of cholangiocarcinoma?**
- **Sequencing in second line**
- **Is liquid biopsy useful in these cancers?**
- **Best agent for FGFR mutation patients**
- **Should we check the mutation status upfront or at disease relapse?**

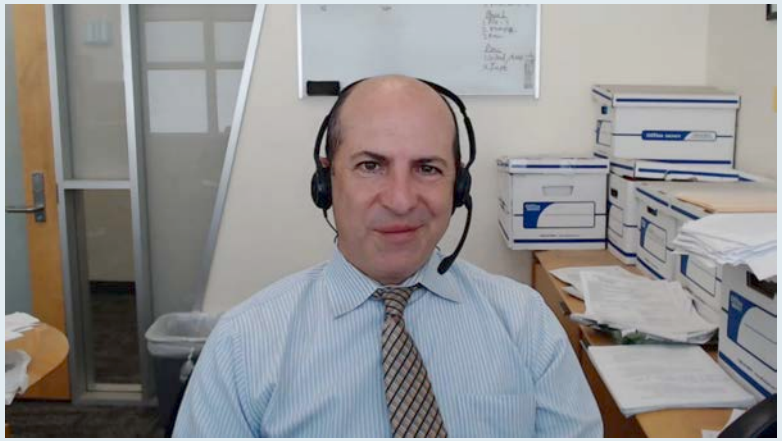
Premeeting survey: July 2021

# What somatic and/or germline testing, if any, should be performed in cholangiocarcinoma?

Dr Dustin Deming

Prof Eric Van Cutsem

TikTonc



Dr Zev Wainberg

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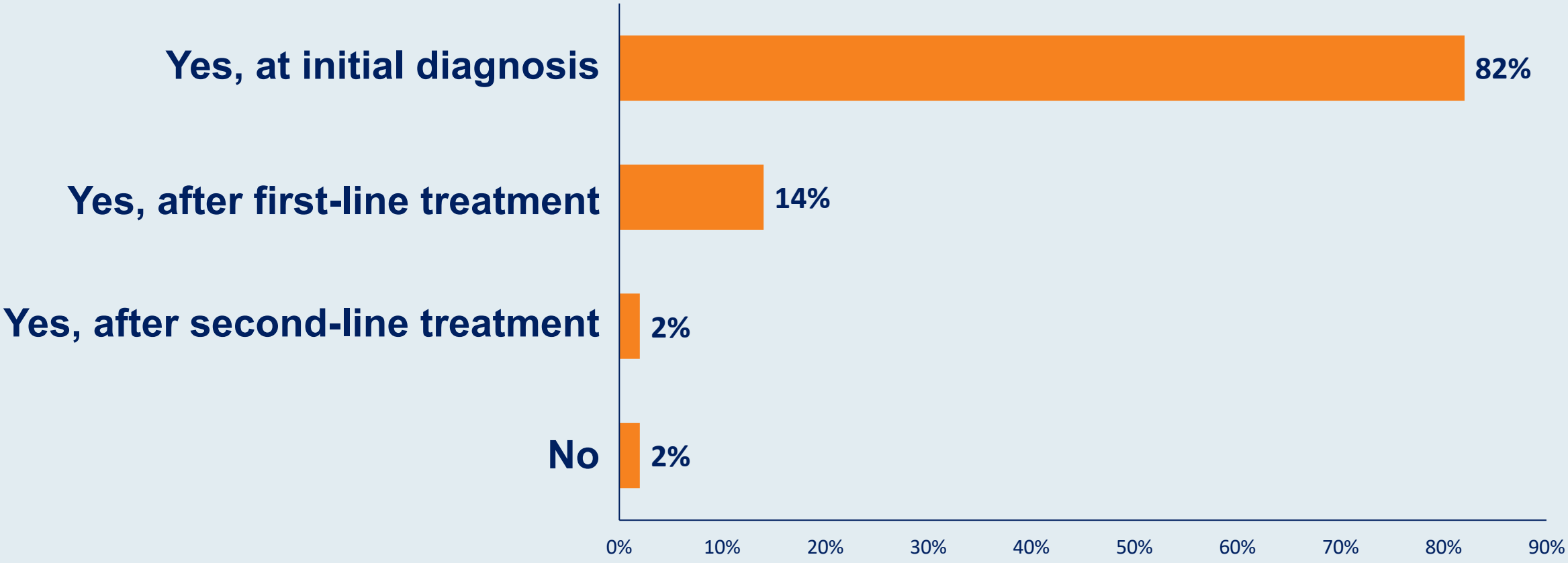
TO PRACTICE

# Do you routinely test for targetable mutations in your patients with metastatic cholangiocarcinoma?




Premeeting survey: July 2021

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RESEARCH
TO PRACTICE

# Do you routinely test for targetable mutations in your patients with metastatic cholangiocarcinoma?

| | | | |
|---|---|---|---|
|  Dr Bekaii-Saab | Yes, at initial diagnosis |  Dr Atreya | Yes, at initial diagnosis |
|  Dr O'Reilly | Yes, at initial diagnosis |  Dr Deming | Yes, at initial diagnosis |
|  Dr Philip | Yes, at initial diagnosis |  Prof Van Cutsem | Yes, at initial diagnosis |
|  Dr Reiss Binder | Yes, at initial diagnosis |  Dr Wainberg | Yes, at initial diagnosis |

RTP RESEARCH TO PRACTICE

# Should community-based medical oncologists be testing for targetable mutations in all patients with metastatic cholangiocarcinoma? When in the treatment course is the optimal time to do so, and what platform(s) should be used?

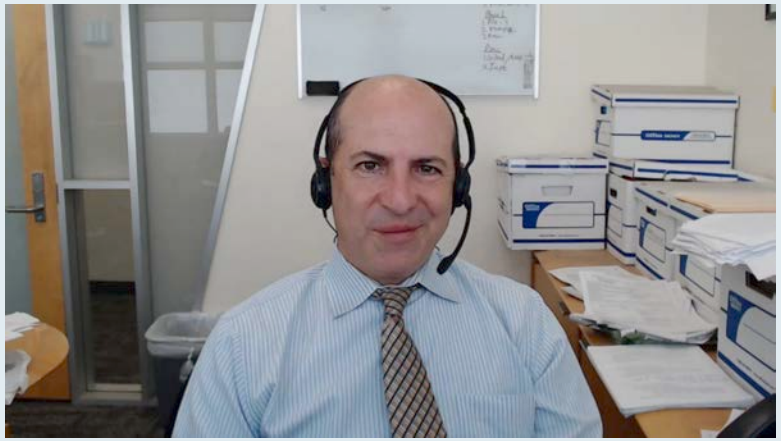
- All patients with advanced CCA should be tested for targetable alterations
- NGS testing with preferably both DNA and RNA-based assays
- “Liquid” biopsies acceptable if tissue not accessible
- Testing must be performed at time of initial visit

# How often are FGFR2 translocations observed in cholangiocarcinoma? What are the risks and benefits of FGFR2 inhibitors?

Dr Dustin Deming

Prof Eric Van Cutsem

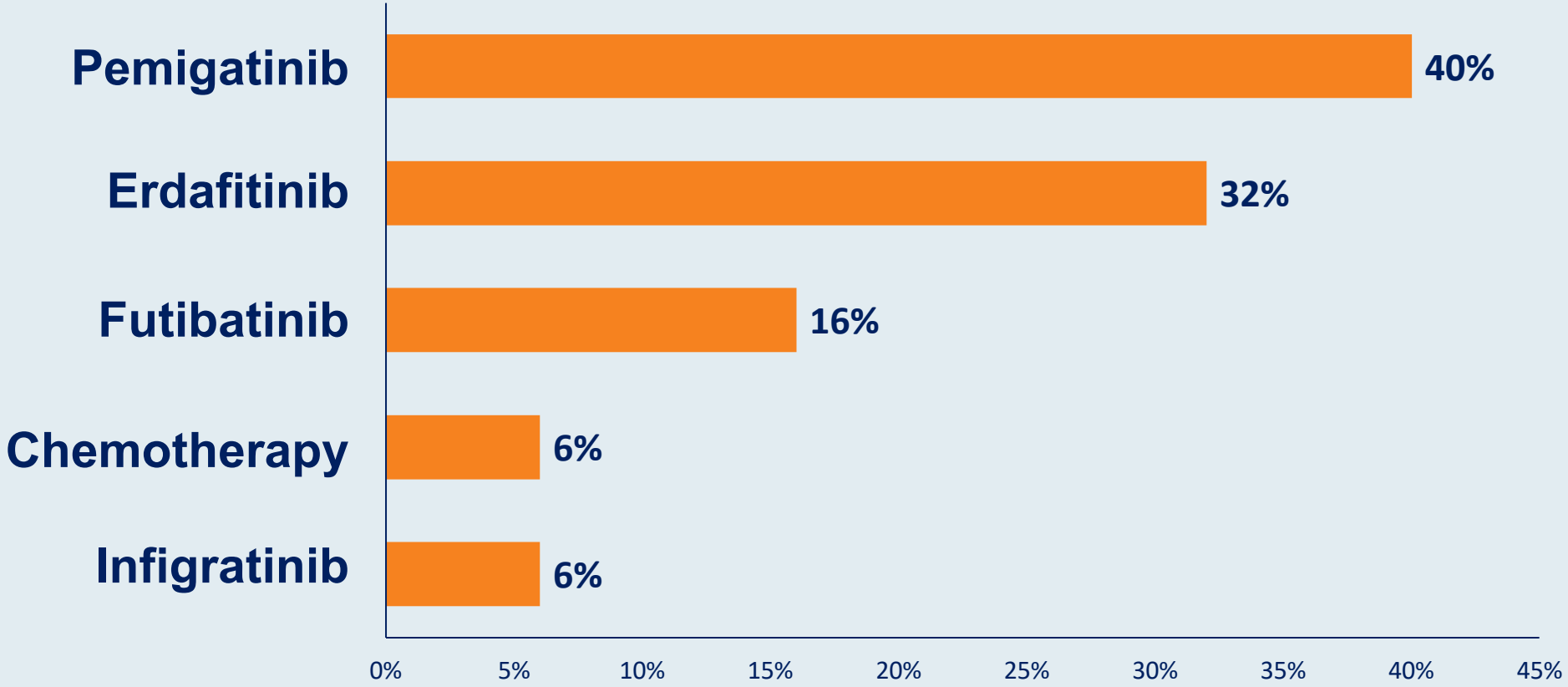
TikTonc



Dr Zev Wainberg

RTP RESEARCH TO PRACTICE

# Regulatory and reimbursement issues aside and assuming all of these agents were available, what would be your preferred second-line systemic treatment for a 65-year-old patient with metastatic cholangiocarcinoma with an FGFR2 fusion who experienced disease progression on first-line cisplatin/gemcitabine?




Premeeting survey: July 2021

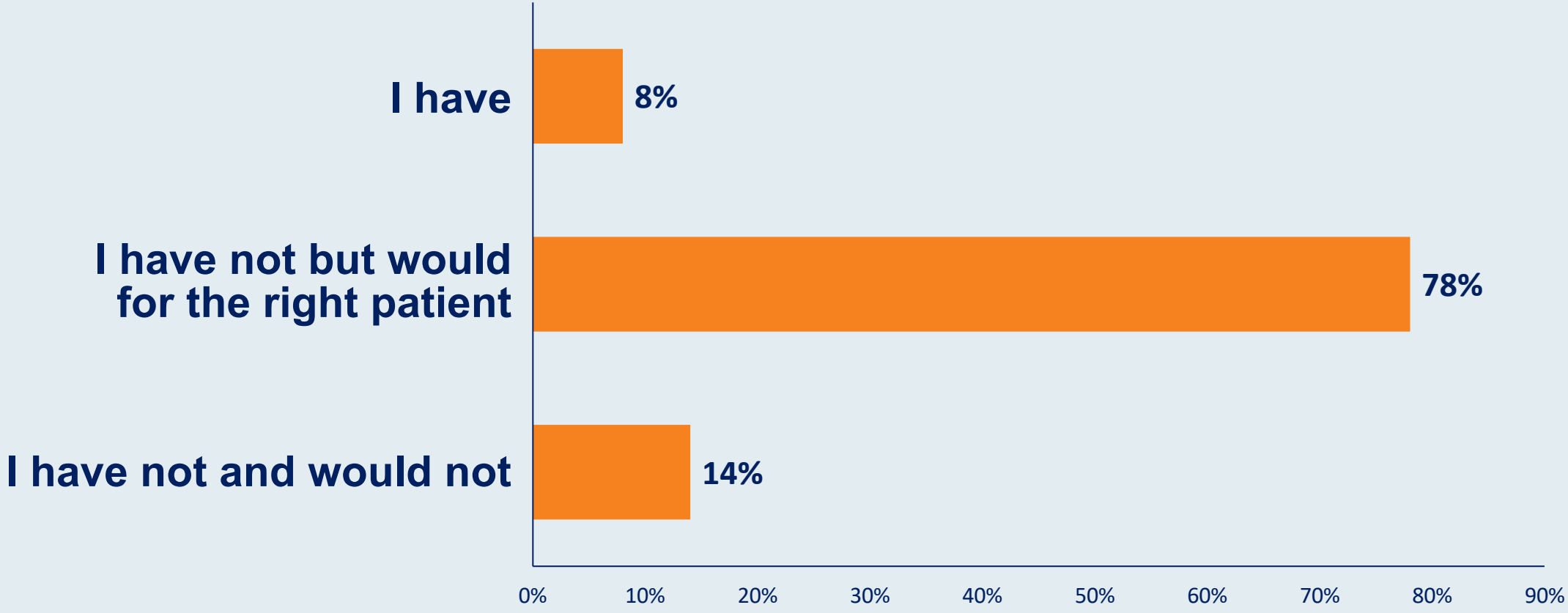
RTP RESEARCH TO PRACTICE

# Regulatory and reimbursement issues aside and assuming all of these agents were available, what would be your preferred second-line systemic treatment for a 65-year-old patient and metastatic cholangiocarcinoma with an FGFR2 fusion who experiences disease progression on first-line cisplatin/gemcitabine?

| | | | |
|---|---|---|---|
|  Dr Bekaii-Saab | Pemigatinib |  Dr Atreya | Infigratinib |
|  Dr O'Reilly | Pemigatinib |  Dr Deming | Pemigatinib or Futibatinib |
|  Dr Philip | Pemigatinib |  Prof Van Cutsem | Pemigatinib |
|  Dr Reiss Binder | Pemigatinib |  Dr Wainberg | Pemigatinib or Infigratinib or Futibatinib |

RTP RESEARCH TO PRACTICE

# Have you administered or would you administer an FGFR inhibitor as first-line therapy to a patient with metastatic cholangiocarcinoma with an FGFR2 fusion who could not tolerate or did not wish to receive chemotherapy?




Premeeting survey: July 2021

RTP RESEARCH TO PRACTICE

# Have you or would you administer an FGFR inhibitor as first-line therapy to a patient with metastatic cholangiocarcinoma with an FGFR2 fusion who could not tolerate or did not wish to receive chemotherapy?

| | | | |
|---|---|---|---|
|  Dr Bekaii-Saab | I have not and would not |  Dr Atreya | I have not but would for the right patient |
|  Dr O'Reilly | I have |  Dr Deming | I have |
|  Dr Philip | I have not but would for the right patient |  Prof Van Cutsem | I have |
|  Dr Reiss Binder | I have not but would for the right patient |  Dr Wainberg | I have not and would not |

RTP RESEARCH TO PRACTICE

**What is the optimal therapeutic approach for a patient with metastatic cholangiocarcinoma with an FGFR2 fusion who has experienced disease progression on first-line cisplatin/gemcitabine? Do you believe there are significant differences among the approved and investigational FGFR inhibitors in cholangiocarcinoma that will ultimately result in superior efficacy or safety for one over the others?**

- FGFR targeted agents approved by FDA for use include pemigatinib and infigratinib
  - Efficacy similar but toxicities may be slightly worse with infigratinib .
- Futibatinib = irreversible inhibitor that may exhibit activity when other agents fail
  - Similar activity to both approved agents
- Others ( Erdafitinib, Debio 1347 and Derazantinib)

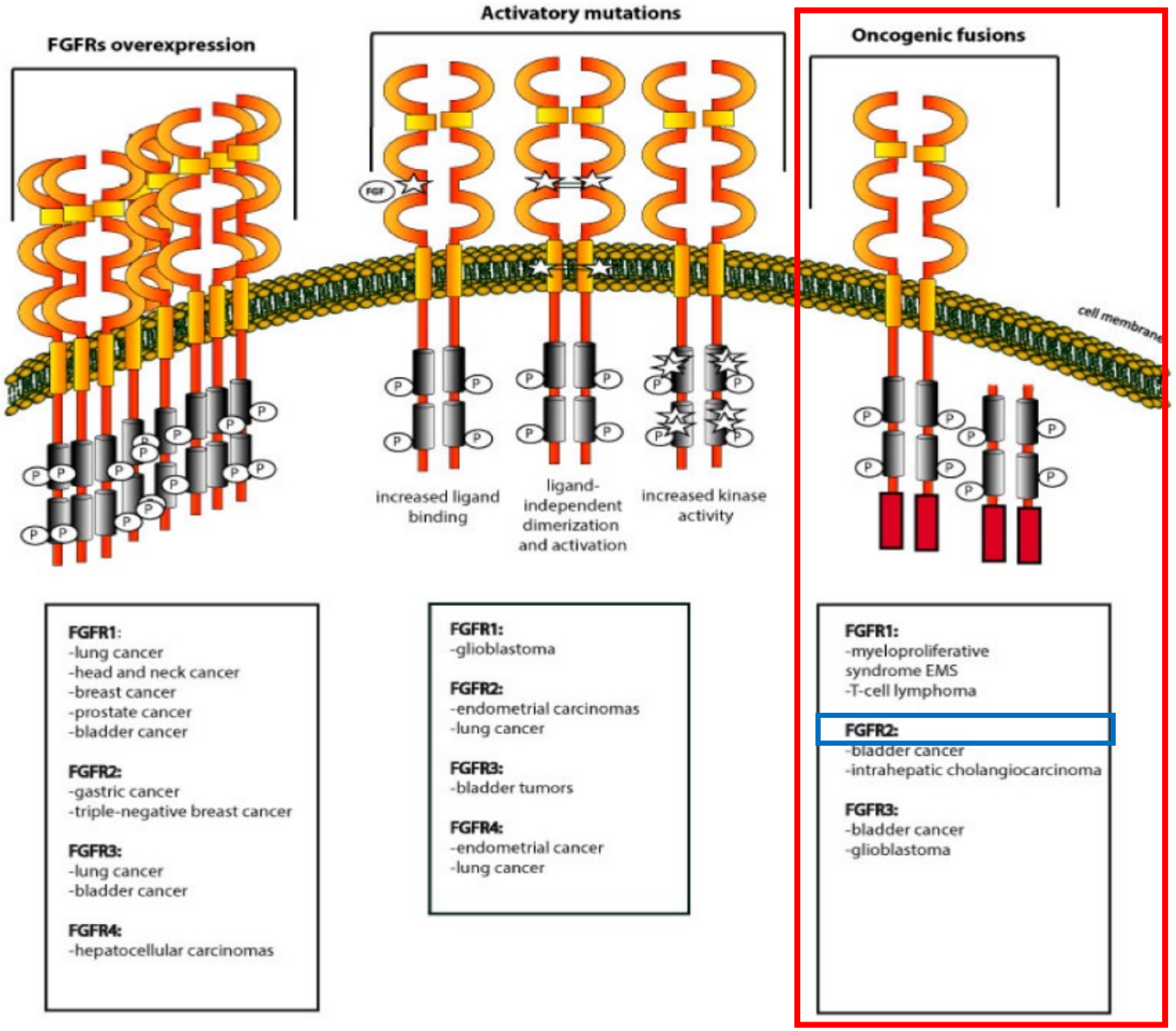
# Questions for the Faculty from Webinar Registrants – Cholangiocarcinoma

- **Options for 75-yo man with ECOG 2 bile duct cancer, not enough cells for NGS, liquid biopsy c/w CHIP, other than carboplatin/gemcitabine?**
- **When do you offer neoadjuvant chemo for cholangiocarcinoma?**
- **Would you use IO therapy for TMB >10?**
- **Most people don't harbor FGFR mutation in cholangiocarcinoma, which regimen do you use upon progression after cisplatin/gemcitabine?**

Premeeting survey: July 2021

RTP RESEARCH TO PRACTICE

# Targeting Dysregulation of FGFR in BTC



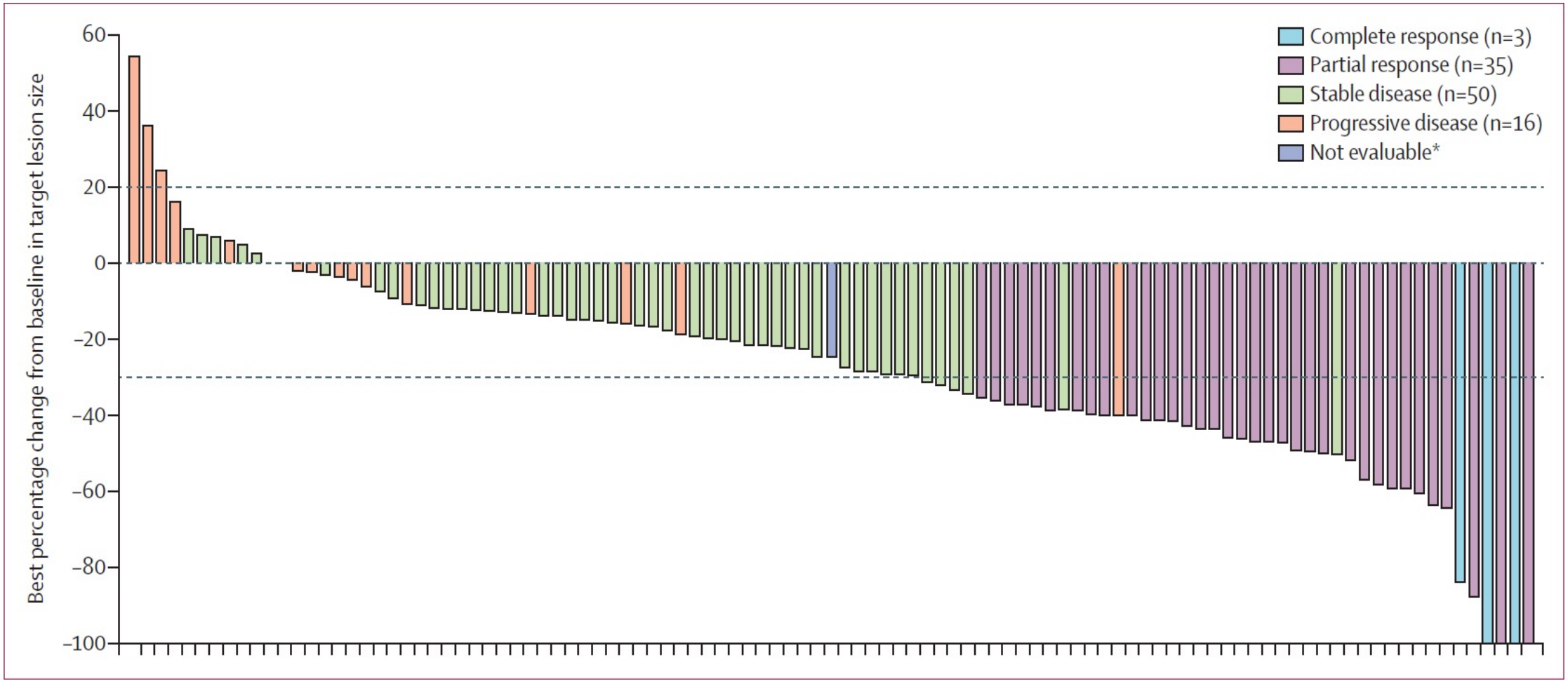

Agents in Development:

- Pemigatinib
- Infigratinib
- Futibatinib
- Derazantinib
- And others

Borad M et al. Current Opinion in Gastroenterology. May 2015

Courtesy of Tanios Bekaii-Saab, MD

# FIGHT 202: Pemigatinib in Patients With iCCA Harboring *FGFR2* Fusions or Rearrangements




Colored bars indicate confirmed responses assessed by RECIST 1·1. FGFR, fibroblast growth factor receptor. RECIST 1.1, Response Evaluation Criteria in Solid Tumors version 1.1. *Patient had a decrease in target lesion size but was not evaluable for response using RECIST.

Abou-Alfa GK et al. *Lancet Oncol*. 2020;21(5):671-684.

Courtesy of Tanios Bekaii-Saab, MD

# Phase 2 FIGHT-202 Trial: Safety

| Adverse Event, n (%) | All Grades | Grade ≥3 |
|---|---|---|
| Hyperphosphatemia | 81 (55%) | 0 |
| Alopecia | 67 (46%) | 0 |
| Dysgeusia | 55 (38%) | 0 |
| Diarrhea | 49 (34%) | 4 (3%) |
| Fatigue | 45 (31%) | 2 (1%) |
| Stomatitis | 39 (27%) | 8 (5%) |
| Dry mouth | 42 (29%) | 0 |
| Nausea | 34 (23%) | 2 (1%) |
| Decreased appetite | 34 (23%) | 1 (1%) |
| Dry eye | 30 (21%) | 1 (1%) |
| Dry skin | 22 (15%) | 1 (1%) |
| Arthralgia | 16 (11%) | 6 (4%) |
| Palmar-plantar erythrodysaethesia | 16 (11%) | 6 (4%) |

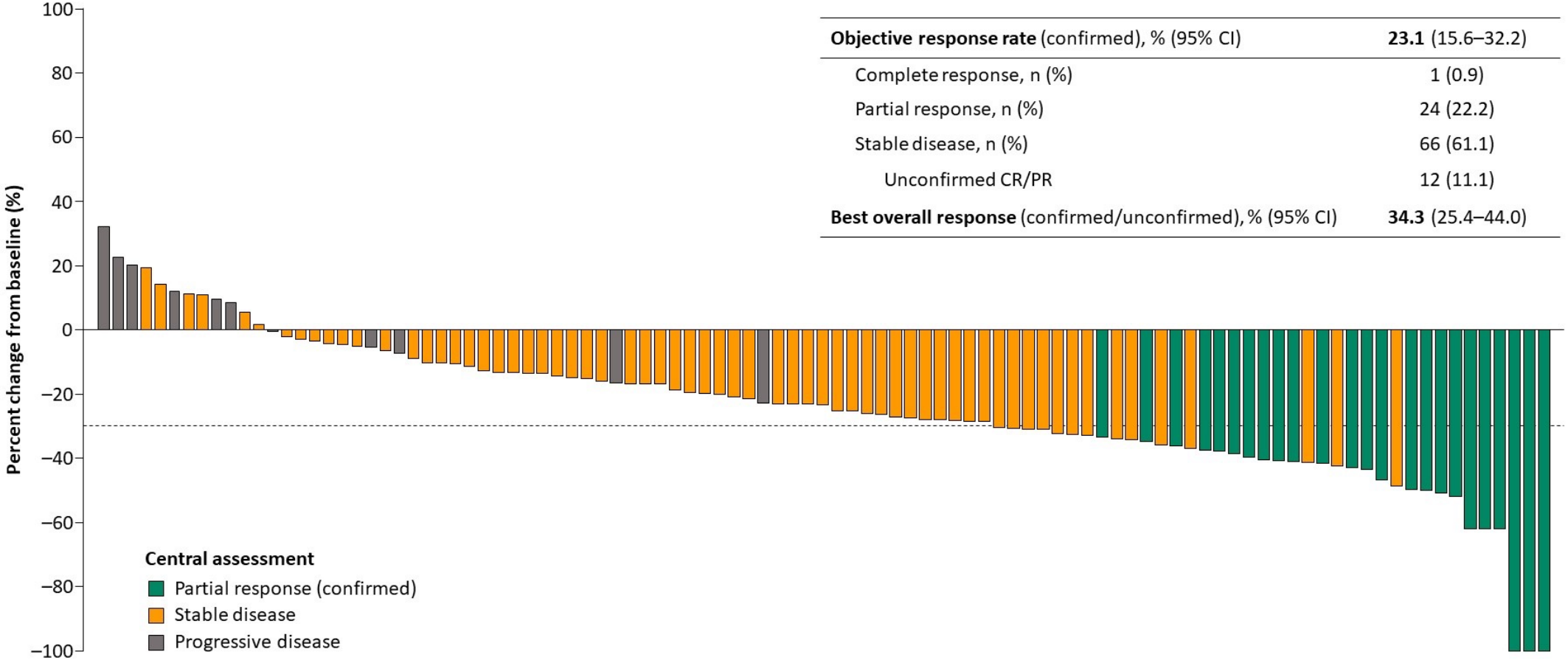
- Hyperphosphatemia managed with a low-phosphate diet, phosphate binders, and diuretics, or dose reduction/interruption
  - All grade 1 or 2
  - Few (n = 3) required dose reductions/interruptions
- Hypophosphatemia occurred in 23% of patients
  - Most common grade ≥3 AEs (12%)
  - None clinically significant/serious; none led to discontinuation/dose reduction
- Serous retinal detachment occurred in 4% of patients
  - Mostly grade 1/2 (grade ≥3, 1%)
  - None resulted in clinical sequelae

Abou-Alfa GK et al. *Lancet Oncol*. 2020;21(5):671-684.

Courtesy of Tanios Bekaii-Saab, MD

# Phase II Trial of Infigratinib

## Best percentage change in target-lesion size: ORR confirmed responses by BICR



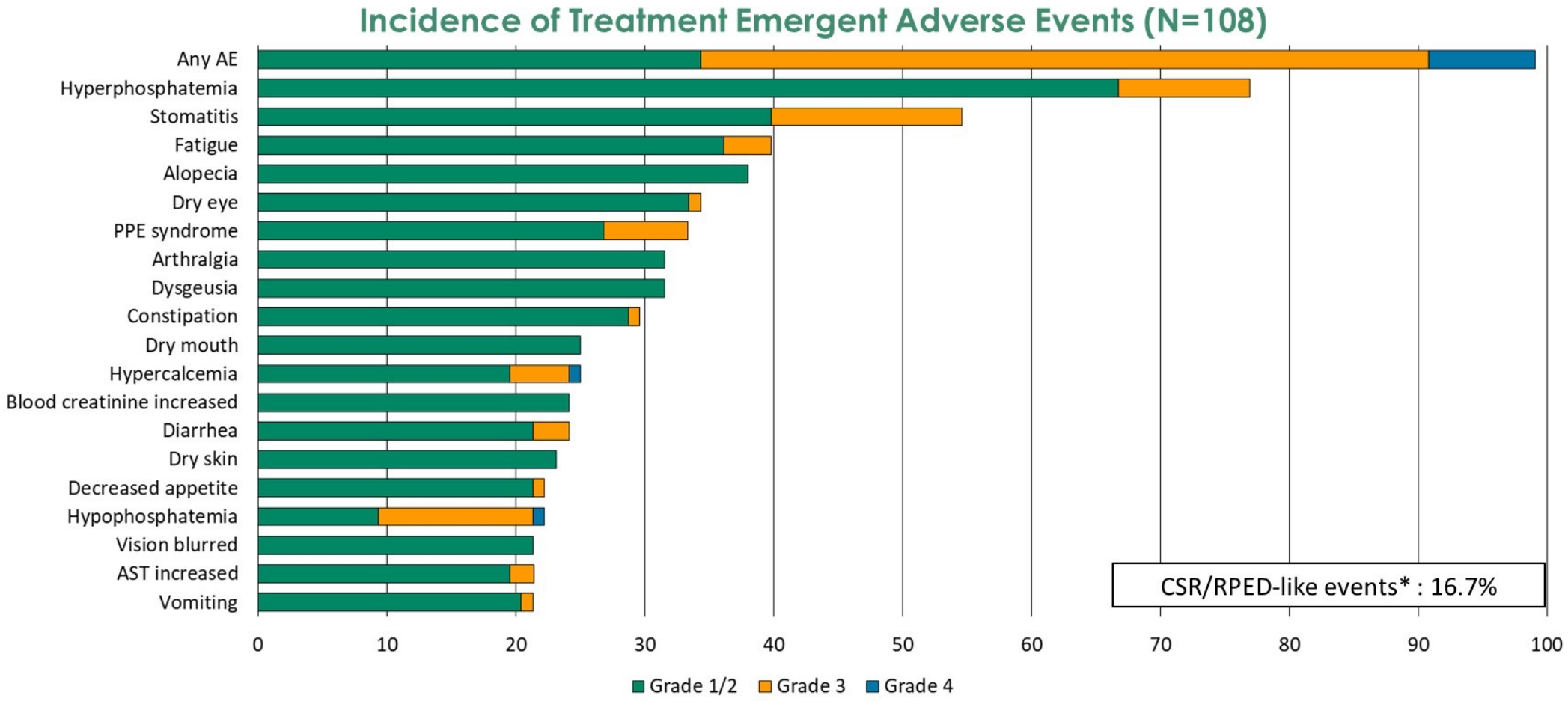

| | |
|---|---|
| **Objective response rate** (confirmed), % (95% CI) | **23.1** (15.6–32.2) |
| Complete response, n (%) | 1 (0.9) |
| Partial response, n (%) | 24 (22.2) |
| Stable disease, n (%) | 66 (61.1) |
| Unconfirmed CR/PR | 12 (11.1) |
| **Best overall response** (confirmed/unconfirmed), % (95% CI) | **34.3** (25.4–44.0) |

Only patients with measurable disease at baseline and with at least one post-baseline scan are shown in the waterfall plot (n=100)

Presented By Milind Javle at 2021 Gastrointestinal Cancers Symposium

Courtesy of Tanios Bekaii-Saab, MD

# Infigratinib safety profile
# Most common treatment-emergent adverse events (> 20%)




*Central serous retinopathy (CSR)/retinal pigment epithelial detachment (RPED)-like events included the following terms: chorioretinopathy; subretinal fluid; serous retinal detachment; and detachment of retinal pigment epithelium, macular detachment, and retinopathy

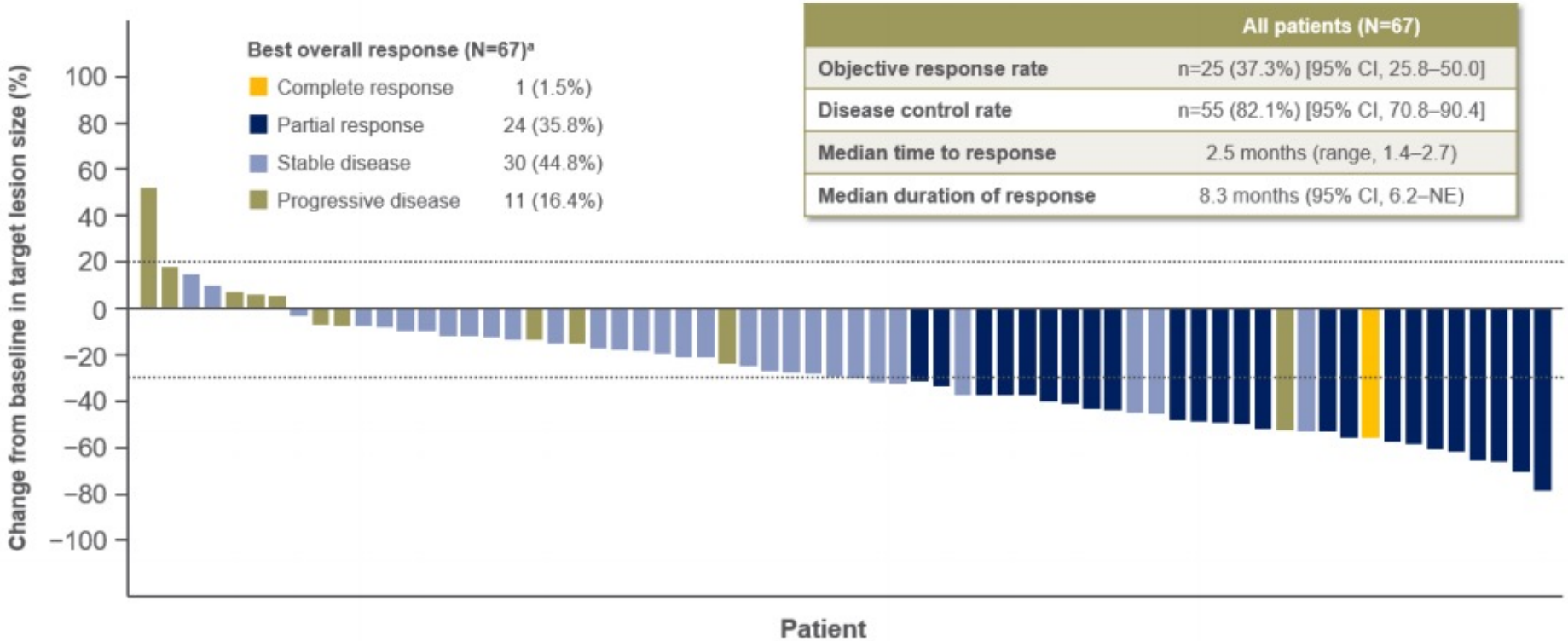
Presented By Milind Javle at 2021 Gastrointestinal Cancers Symposium

Courtesy of Tanios Bekaii-Saab, MD

FOENIX CCA2

# Efficacy of Futibatinib in Patients With iCCA

- Futibatinib demonstrated objective and durable responses in an interim analysis of the phase 2 FOENIX-CCA2 (NCT02052778) study of patients with advanced/refractory intrahepatic cholangiocarcinoma (iCCA) harboring *FGFR2* fusions/rearrangements (see ESMO poster #54P)




| | All patients (N=67) |
|---|---|
| Objective response rate | n=25 (37.3%) [95% CI, 25.8–50.0] |
| Disease control rate | n=55 (82.1%) [95% CI, 70.8–90.4] |
| Median time to response | 2.5 months (range, 1.4–2.7) |
| Median duration of response | 8.3 months (95% CI, 6.2–NE) |

CI, confidence interval; iCCA, intrahepatic cholangiocarcinoma; NE, not evaluable; RECIST v1.1, Response Evaluation Criteria in Solid Tumors version 1.1.
Dashed horizontal lines represent the ≥30% reduction in lesion size defined as a partial response and a ≥20% increase in lesion size as progressive disease, per RECIST v1.1.
[a]One patient was not evaluable.

Courtesy of Tanios Bekaii-Saab, MD

FOENIX CCA2

# Safety of Futibatinib in Patients With iCCA

- Futibatinib also had a tolerable and manageable safety profile in the FOENIX-CCA2 study
- The most common any-grade treatment-related adverse events (TRAEs) were hyperphosphatemia (81%), diarrhea (37%), and dry mouth (33%)

| | Safety population (N=67), n (%)[a] | |
|---|---|---|
| | Any grade | Grade 3[b] |
| **TRAEs** | 67 (100) | 38 (57) |
| **Most common TRAEs (by preferred term)** | | |
| Hyperphosphatemia | 54 (81) | 18 (27) |
| Diarrhea | 25 (37) | 0 |
| Dry mouth | 22 (33) | 0 |
| **Serious TRAEs** | 7 (10) | |
| **Study drug modifications due to TRAEs** | 44 (66) | |
| Drug interruption | 37 (55) | |
| Drug dose reduction | 34 (51) | |
| Withdrawal of drug | 1 (1) | |
| **TRAEs with an outcome of death** | 0 | |

iCCA, intrahepatic cholangiocarcinoma; TRAE, treatment-related adverse event.
[a]AEs were recorded between the first dose and for 30 days after the last dose of study drug. Patients with ≥2 AEs in any category are counted once.
[b]No grade 4 or 5 TRAEs were reported.

Courtesy of Tanios Bekaii-Saab, MD

# FGFR Inhibitor Efficacy in *FGFR2* Fusion CCA

| | Pemigatinib* ( N=107) | Infigratinib* (N=108) | Futibatinib (N=67) | Derazantinib (N=29) |
|---|---|---|---|---|
| ORR | 35.5% | 34.3% | 37.3% | 20.7% |
| DCR | 82.2% | 83.1% | 82.1% | 82.85 |
| mPFS | 6.9 mos | 6.8 mos | 7.2 mos | 5.7 mos |
| mOS | 21.1 mos | 12.5 mos | NR | NR |
| Toxicities | Hyperphosphatemia, Alopecia, Diarrhea | Hyperphosphatemia, Stomatitis, Fatigue | Hyperphosphatemia, Diarrhea, Dry mouth | Hyperphosphatemia, Fatigue, Ocular |

*FDA Approved

1. Javle M et al. ASCO GI 2021; 2. Abou-Alfa GK et al. *Lancet Oncol*. 2020;21(5):671-684; 3. Goyal L et al. ASCO 2020; 4. Mazzaferro V et al. *Br J Cancer*. 2019;120(2):165-171.

Courtesy of Tanios Bekaii-Saab, MD

# *Meet The Professor*

# Optimizing the Selection and Sequencing of Therapy for Patients with Renal Cell Carcinoma

**Friday, August 6, 2021**
**12:00 PM – 1:00 PM ET**

## Faculty

**Thomas Powles, MBBS, MRCP, MD**

## Moderator

**Neil Love, MD**

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*Thank you for joining us!*

*CME and MOC credit information will be emailed to each participant within 2-3 business days.*

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