













EPICS

# Global Perspectives in Gastrointestinal Malignancies in 2022 and Beyond

## Full Report

17 and 23 September 2022

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## VIRTUAL CLOSED-DOOR ROUNDTABLE



**DATE:**  
17 and 23  
September 2022



**DISEASE-STATE AND  
DATA PRESENTATIONS**  
by key experts



**INSIGHTS REPORT**  
including postmeeting  
analyses and actionable  
recommendations



**PANEL:** Key experts in  
gastrointestinal (GI)  
malignancies  
> 8 from the US and  
3 from the EU



**GI CANCER-SPECIFIC  
DISCUSSIONS** on  
therapeutic advances and  
their application in clinical  
decision-making

# Day 1: Panel Consisting of 5 US and 3 European GI Cancer Experts

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**Joleen Hubbard, MD**  
Mayo Clinic, Rochester



**Philip A. Philip, MD, PhD**  
Henry Ford Cancer Institute



**Christopher Lieu, MD**  
University of Colorado  
Cancer Center



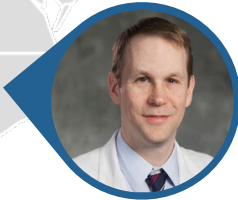
**Gerald Prager, MD, PhD**  
University of Vienna



**Julien Taieb, MD, PhD**  
Georges Pompidou  
European Hospital



**John H. Strickler, MD**  
Duke Cancer Center



**Chiara Cremolini, MD, PhD**  
University of Pisa



**CHAIR**  
**Tanios Bekaii-Saab, MD, FACP**  
Mayo Clinic Cancer Center



# Meeting Agenda Day 1

Time (EST)	Topic	Speaker/Moderator
9.00 AM – 9.05 AM	Welcome and Introductions	Tanios Bekaii-Saab, MD, FACP
9.05 AM – 9.15 AM	Metastatic Colorectal Cancer – Chemotherapy, Targeted Therapies, and Biomarker-Driven Treatments	Joleen Hubbard, MD
9.15 AM – 9.50 AM	Discussion: Metastatic Colorectal Cancer – Chemotherapy, Targeted Therapies, and Biomarker-Driven Treatments	All
9.50 AM – 9.55 AM	Summary of Key Takeaways	Joleen Hubbard, MD
9.55 AM – 10.05 AM	Colorectal Cancer – Immunotherapy	Gerald Prager, MD, PhD
10.05 AM – 10.40 AM	Discussion: Colorectal Cancer – Immunotherapy	All
10.40 AM – 10.45 AM	Summary of Key Takeaways	Gerald Prager, MD, PhD
10.45 AM – 10.55 AM	Break	
10.55 AM – 11.05 AM	Hepatocellular Carcinoma	Philip A. Philip, MD, PhD
11.05 AM – 11.50 AM	Discussion: Hepatocellular Carcinoma	All
11.50 AM – 11.55 AM	Summary of Key Takeaways	Philip A. Philip, MD, PhD
11.55 AM – 12.00 PM	Meeting Close	Tanios Bekaii-Saab, MD, FACP



# Day 2: Panel Consisting of 6 US and 2 European GI Cancer Experts

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**Philip A. Philip, MD, PhD**  
Henry Ford Cancer Institute



**Efrat Dotan, MD**  
Fox Chase Cancer Center



**Alan P. Venook, MD**  
Helen Diller Family  
Comprehensive Cancer Center



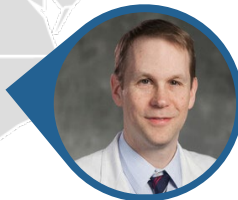
**Gerald Prager, MD, PhD**  
University of Vienna



**CHAIR**  
**Tanios Bekaii-Saab, MD, FACP**  
Mayo Clinic Cancer Center



**John H. Strickler, MD**  
Duke Cancer Center



**Julien Taieb, MD, PhD**  
Georges Pompidou  
European Hospital



**Scott Kopetz, MD, PhD, FACP**  
MD Anderson Cancer Center



# Meeting Agenda Day 2

Time (EST)	Topic	Speaker/Moderator
9.00 AM – 9.05 AM	Welcome and Introductions	Tanios Bekaii-Saab, MD, FACP
9.05 AM – 9.15 AM	Gastroesophageal Junction (GEJ) and Gastric Cancer	Julien Taieb, MD, PhD
9.15 AM – 10.05 AM	Discussion: Gastroesophageal Junction (GEJ) and Gastric Cancer	All
10.05 AM – 10.10 AM	Summary of Key Takeaways	Julien Taieb, MD, PhD
10.10 AM – 10.20 AM	Rectal Cancer	Alan P. Venook, MD
10.20 AM – 11.05 AM	Discussion: Rectal Cancer	All
11.05 AM – 11.10 AM	Summary of Key Takeaways	Alan P. Venook, MD
11.10 AM – 11.20 AM	Break	
11.20 AM – 11.30 AM	Pancreatic Cancer and Biliary Tract Cancer	Efrat Dotan, MD
11.30 AM – 12.20 PM	Discussion: Pancreatic Cancer and Biliary Tract Cancer	All
12.20 PM – 12.25 PM	Summary of Key Takeaways	Efrat Dotan, MD
12.25 PM – 12.30 PM	Meeting Close	Tanios Bekaii-Saab, MD, FACP



**EPICS****Metastatic Colorectal Cancer –  
Chemotherapy, Targeted  
Therapies, and Biomarker-Driven  
Treatments**





# Metastatic CRC – Chemotherapy, Targeted Therapies, and Biomarker-Driven Treatments (1/4)

Presented by Joleen Hubbard, MD

**KRAS G12C mutation**  
 > KRAS G12C mutations occur in 3%–5% of mCRC patients

**KRAS G12C**  
 > Data from the phase Ib CodeBreak 101 study, of sotorasib in





# Metastatic CRC – Chemotherapy, Targeted Therapies, and Biomarker-Driven Treatments (2/4)

Presented by Joleen Hubbard, MD

## HER2 amplification

> HER2 amplification/overexpression occurs in ~3%–5% of all patients with mCRC

**STUDY POPULATION**

HER2 amplification/overexpression was defined as a HER2/CEP17 ratio  $\geq 2.0$  by FISH or IHC 3+ staining. The study population consisted of 1,000 patients with mCRC who were treated with a fluoropyrimidine, oxaliplatin, and irinotecan combination therapy. The study population was divided into two groups: 300 patients with HER2 amplification/overexpression and 700 patients without HER2 amplification/overexpression. The study population was further divided into two groups based on treatment: 500 patients who received treatment through week 16 and 500 patients who received treatment through week 24.

**RESULTS**

The overall response rate (ORR) was significantly higher in the HER2 amplification/overexpression group compared to the non-HER2 amplification/overexpression group (15.0% vs 10.0%,  $p < 0.05$ ). The median overall survival (OS) was significantly longer in the HER2 amplification/overexpression group compared to the non-HER2 amplification/overexpression group (18.0 months vs 14.0 months,  $p < 0.05$ ).

**KEY TAKEAWAYS**

HER2 amplification/overexpression is a biomarker for improved outcomes in mCRC patients treated with fluoropyrimidine, oxaliplatin, and irinotecan combination therapy. HER2 amplification/overexpression is associated with a higher ORR and longer OS compared to non-HER2 amplification/overexpression.





# Metastatic CRC – Chemotherapy, Targeted Therapies, and Biomarker-Driven Treatments (3/4)

Presented by Joleen Hubbard, MD

## VEGF inhibitors

> Fruquintinib is a tyrosine kinase inhibitor of VEGFR-1, -2, and -3

### STUDY POPULATION

1. 1000 patients with metastatic CRC, ECOG performance grade 0-1, who had received prior systemic therapy for metastatic disease. Patients were randomized to receive either fruquintinib (n=500) or placebo (n=500) in combination with best supportive care. The primary endpoint was overall survival (OS). The secondary endpoint was progression-free survival (PFS). The median OS was 11.1 months in the fruquintinib group and 10.1 months in the placebo group. The median PFS was 4.1 months in the fruquintinib group and 3.8 months in the placebo group.

### RESULTS

2. OS was significantly improved in the fruquintinib group compared to the placebo group (p=0.001). The median OS was 11.1 months in the fruquintinib group and 10.1 months in the placebo group. The median PFS was 4.1 months in the fruquintinib group and 3.8 months in the placebo group.

### KEY TAKEAWAYS

3. Fruquintinib significantly improved OS compared to placebo in patients with metastatic CRC. Fruquintinib also improved PFS compared to placebo.

### OS: Fruquintinib vs Placebo



### RESPONSE: Fruquintinib vs Placebo





# Metastatic CRC – Chemotherapy, Targeted Therapies, and Biomarker-Driven Treatments (4/4)

Presented by Joleen Hubbard, MD

## Presenter's conclusions

### STUDY POPULATION

1. 10,000 patients with metastatic CRC, average age 65, 50% male, 50% female, 50% white, 30% black, 15% hispanic, 5% other. Average 10% performance. 50% of patients with metastatic CRC are treated with systemic chemotherapy agents. 50% of patients with metastatic CRC are treated with targeted therapies. 50% of patients with metastatic CRC are treated with immunotherapy. 50% of patients with metastatic CRC are treated with combination therapy.

### RESULTS

2. 50% of patients with metastatic CRC are treated with systemic chemotherapy agents. 50% of patients with metastatic CRC are treated with targeted therapies. 50% of patients with metastatic CRC are treated with immunotherapy. 50% of patients with metastatic CRC are treated with combination therapy.

### KEY TAKEAWAYS

3. Systemic chemotherapy agents are the backbone of treatment for metastatic CRC. Targeted therapies and immunotherapy are used to improve outcomes in patients with specific biomarkers.

### KEY TAKEAWAYS FROM BASKIN ET AL (2018)



### RESPONSE RATES AND TOXICITY IN THE BASKIN ET AL (2018) STUDY



# Metastatic Colorectal Cancer (CRC) – Chemotherapy, Targeted Therapies, and Biomarker-Driven Treatments (1/4)

## First-line chemotherapy backbone

> Overall, in the US and EU, FOLFOX is the preferred backbone option with anti-EGFR therapy and, depending on the toxicity profile,

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# Metastatic Colorectal Cancer (CRC) – Chemotherapy, Targeted Therapies, and Biomarker-Driven Treatments (2/4)

## RAS wild-type

> Data from the FRESCO-2 study (LBA 25) are regarded as impactful and experts agreed fruquintinib will become another treatment choice in later lines post-

regorafenib or post TAC 100 in the metastatic setting. “fruquintinib is probably coming to us in the clinic.” “We have so many patients every week in later

lines who are not responding to standard of care. Fruquintinib is a great option for a patient who is not responding to standard of care.”

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# Metastatic Colorectal Cancer (CRC) – Chemotherapy, Targeted Therapies, and Biomarker-Driven Treatments (3/4)

## HER2 amplification

> The data from the MOUNTAINEER study of tucatinib and trastuzumab (LBA27) are convincing, and OS for these

patients appears to be similar to that seen in the HER2+ metastatic breast cancer setting.

Phase III study of tucatinib and trastuzumab in HER2+ metastatic CRC. OS for these patients appears to be similar to that seen in the HER2+ metastatic breast cancer setting.

The approach to use an effective, existing, well-tolerated, well-studied, well-understood drug.

Phase III study of tucatinib and trastuzumab in HER2+ metastatic CRC. OS for these patients appears to be similar to that seen in the HER2+ metastatic breast cancer setting.

The approach to use an existing, well-studied, well-understood drug in a setting where the drug is already used.

Phase III study of tucatinib and trastuzumab in HER2+ metastatic CRC. OS for these patients appears to be similar to that seen in the HER2+ metastatic breast cancer setting.

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# Metastatic Colorectal Cancer (CRC) – Chemotherapy, Targeted Therapies, and Biomarker-Driven Treatments (4/4)

## NGS

> In the US, community centers often send out their samples to third-party testing facilities, which may be more robust than



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# Colorectal Cancer – Immunotherapy



# Colorectal Cancer – Immunotherapy (1/2)

Presented by Gerald Prager, MD, PhD

## dMMR/MSI-H CRC

> In the NICHE-2 study in locally advanced MMR-deficient colon cancer (LBA7), patients were treated with neoadjuvant ipi plus nivo, and

*[Blurred text from a slide, likely containing details about the NICHE-2 study results.]*





# Colorectal Cancer – Immunotherapy (2/2)

Presented by Gerald Prager, MD, PhD

## ICI plus targeted therapy

Data were summarized from

*[Blurred text area containing source information]*



### Neoadjuvant use of immune checkpoint inhibitors (ICIs) in dMMR/MSI-H CRC

> “The early data that we have seen in the neoadjuvant setting really does suggest that when you are not dealing with stage 4, the impact of immunotherapy

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### ICI in MSI-high metastatic disease

> Overall, experts use single-agent pembrolizumab in the first line, unless there is a need for a quick response in a patient who has extensive

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# Hepatocellular Carcinoma



# Hepatocellular Cancer (1/2)

Presented by Philip A. Philip, MD, PhD

## Second-line treatment

> Updated data from the KEYNOTE-240 study of pembro vs placebo in sorafenib-treated, advanced hepatocellular carcinoma were presented





# Hepatocellular Cancer (2/2)

Presented by Philip A. Philip, MD, PhD

## Sequencing

> “This is what I think of the sequencing. The first question will be, is atezo plus bev a possibility?”

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## Frontline treatment

> Atezo plus bevacizumab remains the treatment of choice for patients eligible for this regimen: *“Nothing has succeeded to beat the atezo plus bev, sometimes*

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## Clinical trials

> The challenge with many of the trials showing positive data remains the selection of Child-Pugh A patients, and Child-Pugh B 7 and 8

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# Gastroesophageal Junction and Gastric Cancer



# GEJ and Gastric Cancer (1/4)

Presented by Julien Taieb, MD, PhD

## HER2-positive GEJ and gastric cancer

> Updated analysis of the phase II DESTINY-Gastric02 in Western patients was presented (1205MO): “Trastuzumab deruxtecan conjugate

*[Blurred text area containing detailed notes or a list of bullet points related to the clinical trial and treatment.]*

## Timeline of FDA Approvals for HER2+ Breast Cancer

A horizontal timeline showing FDA approvals for HER2+ breast cancer treatments from 2006 to 2022. The timeline is represented by a yellow bar with vertical markers for each year. The treatments listed below the bar are: 2006 (Trastuzumab), 2007 (Trastuzumab emtansine), 2013 (Pertuzumab), 2015 (Trastuzumab deruxtecan), 2017 (Trastuzumab emtansine), 2018 (Trastuzumab deruxtecan), 2019 (Trastuzumab deruxtecan), 2020 (Trastuzumab deruxtecan), 2021 (Trastuzumab deruxtecan), and 2022 (Trastuzumab deruxtecan).

Year	Treatment
2006	Trastuzumab
2007	Trastuzumab emtansine
2013	Pertuzumab
2015	Trastuzumab deruxtecan
2017	Trastuzumab emtansine
2018	Trastuzumab deruxtecan
2019	Trastuzumab deruxtecan
2020	Trastuzumab deruxtecan
2021	Trastuzumab deruxtecan
2022	Trastuzumab deruxtecan





# GEJ and Gastric Cancer (2/4)

Presented by Julien Taieb, MD, PhD

## HER2-negative GEJ and gastric cancer ICI in first-line trials

HER2-negative gastric cancer and gastroesophageal junction (GEJ) cancer are common gastrointestinal malignancies. Immunotherapy, specifically immune checkpoint inhibitors (ICI), has emerged as a promising treatment option. This slide discusses the role of ICI in first-line trials for HER2-negative GEJ and gastric cancer. Key findings from clinical trials, such as the KEYNOTE-059 trial, show that the combination of pembrolizumab with chemotherapy significantly improves overall survival compared to chemotherapy alone in this patient population. The slide also highlights the importance of biomarker testing, such as PD-L1 expression, in selecting patients who may benefit most from ICI. Ongoing research is focused on optimizing the timing and combination of ICI with chemotherapy to further improve outcomes for these patients.





# GEJ and Gastric Cancer (3/4)

Presented by Julien Taieb, MD, PhD

## HER2-negative GEJ and gastric cancer ICI in second-line trials

HER2-negative gastric cancer and gastroesophageal junction (GEJ) cancer are common malignancies. Immunotherapy, particularly immune checkpoint inhibitors (ICI), has emerged as a promising treatment option in the second-line setting. Several clinical trials have evaluated the efficacy and safety of ICI in this population. Key trials include the CheckMate 649 trial, which compared nivolumab plus ipilimumab to nivolumab monotherapy, and the KEYNOTE-062 trial, which compared pembrolizumab to placebo. These trials have shown that ICI can provide meaningful clinical benefits, including improved overall survival and response rates, compared to standard chemotherapy in second-line treatment. The combination of nivolumab and ipilimumab has shown the most promising results, with a statistically significant improvement in overall survival compared to nivolumab monotherapy. These findings support the use of ICI as a second-line treatment option for HER2-negative gastric and GEJ cancer.





# GEJ and Gastric Cancer (4/4)

Presented by Julien Taieb, MD, PhD

## Biomarkers

> The role of DKN-01 and tislelizumab plus chemotherapy as first line in the phase IIa DisTinGuish trial (1213P) showed that *“it will take a bit*

*[Blurred text from a slide, likely containing trial results and biomarker analysis details.]*



> Overall, no practice-changing data were presented at ESMO

**ICI in first line**

> Candidates for ICI are those who have no contraindication for immunotherapy and CPS  $\geq 5$ , patients with MSI-H, as well as those who are EBV





## ICI in the neoadjuvant setting

> There is excitement as to the role of ICI in the neoadjuvant setting, and it will be interesting to see how the field of ICI in the adjuvant or

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## HER2-positive GEJ and gastric cancer

> A proposed treatment sequence for the US is

- 1. Trastuzumab (Herceptin) + capecitabine + epirubicin + fluorouracil (CAEF) + trastuzumab (HER2-targeted therapy) - (NCT01088532, Phase III)
- 2. Promising safety and efficacy results from this combination in an ongoing phase III study of trastuzumab with trastuzumab + capecitabine + epirubicin + fluorouracil (CAEF) - (NCT01088532, Phase III)
- 3. The regimen is seen as effective, meeting with and closely applicable to many settings.
- 4. Trastuzumab + capecitabine + epirubicin + fluorouracil (CAEF) continues to show promising safety and efficacy with durable complete responses - (NCT01088532, Phase III)
- 5. This approach is seen as a good option for a patient population in which going trastuzumab + capecitabine + epirubicin + fluorouracil (CAEF) is difficult. It is seen as effective and safe.
- 6. CAEF + trastuzumab is a phase III, randomized, controlled study to assess safety of trastuzumab + capecitabine + epirubicin + fluorouracil (CAEF) in patients with gastric adenocarcinoma - (NCT01088532, Phase III)
- 7. Results indicate the combination of trastuzumab + capecitabine + epirubicin + fluorouracil (CAEF) is safe. However, they would like to see phase II data to confirm its safety in this setting.
- 8. Long-term analysis from CAEF + trastuzumab is a phase II study of trastuzumab plus trastuzumab + capecitabine + epirubicin + fluorouracil (CAEF) in patients with HER2-positive gastric cancer - (NCT01088532, Phase III)
- 9. The CAEF regimen is seen as useful in the specific patient population with refractory disease. It was noted to be effective, very safe, and well-tolerated. Some of the responses were seen fairly early, though.

## Novel targets

- > CLDN18.2 is considered an interesting target and preliminary data from the Claudin18.2-specific CAR T cells, as well as from zolbetuximab

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## Rectal Cancer



# Rectal Cancer (1/3)

Presented by Alan P. Venook, MD

**Total neoadjuvant therapy (TNT)**  
> “Virtually every study in the US that's been done in the past decade in rectal cancer has used a total neoadjuvant approach as the platform,

*[Blurred text area]*





# Rectal Cancer (2/3)

Presented by Alan P. Venook, MD

**dMMR rectal cancer**  
> The phase II study of dostarlimab in patients with stage II or III MSI-H or dMM rectal cancer was presented (Cercek A, et al. *N Engl J Med*

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# Rectal Cancer (3/3)

Presented by Alan P. Venook, MD

## RAPIDO study

> The trial examines the role of short-course radiotherapy followed by chemotherapy before total mesorectal excision (TME) vs preoperative

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**Different modalities of neoadjuvant chemotherapy remain a standard of care**

> The TNT regimen is widely used. However, it was noted that *“there is a population that we're overtreating here . . . so, while it's very easy to*

*overuse it, it's not always necessary for every patient. It's important to have a discussion with the patient and their family about the benefits and risks of the treatment. The TNT regimen is a standard of care, but it's not the only option. There are other regimens that may be more appropriate for certain patients. The goal is to provide the best possible care for each individual patient. It's important to have a multidisciplinary approach to care, involving the surgeon, medical oncologist, radiation oncologist, and the patient and their family. The goal is to achieve the best possible outcome for the patient, while minimizing side effects and maximizing quality of life. The TNT regimen is a standard of care, but it's not the only option. There are other regimens that may be more appropriate for certain patients. The goal is to provide the best possible care for each individual patient. It's important to have a multidisciplinary approach to care, involving the surgeon, medical oncologist, radiation oncologist, and the patient and their family. The goal is to achieve the best possible outcome for the patient, while minimizing side effects and maximizing quality of life.*

**KEY POINTS**

- The TNT regimen is a standard of care, but it's not the only option.
- It's important to have a discussion with the patient and their family about the benefits and risks of the treatment.
- There are other regimens that may be more appropriate for certain patients.
- The goal is to provide the best possible care for each individual patient.
- It's important to have a multidisciplinary approach to care, involving the surgeon, medical oncologist, radiation oncologist, and the patient and their family.
- The goal is to achieve the best possible outcome for the patient, while minimizing side effects and maximizing quality of life.

**KEY POINTS**

- The TNT regimen is a standard of care, but it's not the only option.
- It's important to have a discussion with the patient and their family about the benefits and risks of the treatment.
- There are other regimens that may be more appropriate for certain patients.
- The goal is to provide the best possible care for each individual patient.
- It's important to have a multidisciplinary approach to care, involving the surgeon, medical oncologist, radiation oncologist, and the patient and their family.
- The goal is to achieve the best possible outcome for the patient, while minimizing side effects and maximizing quality of life.



### Non-operative management of rectal cancer

- > Organ preservation is a goal for many patients, particularly elderly patients with comorbidities who are not fit surgery, and young patients if they have a complete response to neoadjuvant therapy. This has to be a very good discussion with the patients because they really need a tight follow up

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# Pancreatic Cancer and Biliary Tract Cancer



# Pancreatic Cancer and Biliary Tract Cancer (1/3)

Presented by Efrat Dotan, MD

**Locally advanced pancreatic cancer**  
> The phase III randomized trial PRODIGE 29-UCGI 26(NEOPAN) comparing chemotherapy with FOLFIRINOX or gemcitabine in locally

*[Blurred text area]*





# Pancreatic Cancer and Biliary Tract Cancer (2/3)

Presented by Efrat Dotan, MD

## Metastatic pancreatic cancer

- > Extended OS results from the POLO study of active maintenance olaparib in patients with metastatic pancreatic cancer and a germline

*[Blurred text area containing details of the POLO study results, including OS curves and statistical significance.]*





# Pancreatic Cancer and Biliary Tract Cancer (3/3)

Presented by Efrat Dotan, MD

## Metastatic biliary tract cancer

- > Updated OS from the phase III TOPAZ-1 study of durva or placebo plus gemcitabine and cisplatin in patients with advanced biliary tract

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# Pancreatic Cancer and Biliary Tract Cancer (1/4)

## Pancreatic cancer

Locally advanced disease

*[Blurred text block containing medical information]*

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## Pancreatic cancer Biomarkers

*(The content in this section is heavily blurred and illegible. It appears to be a list of items or a table with multiple columns.)*

## Biliary tract cancer

> The challenge with this disease is the associated comorbidities and complications that may arise



## Biliary tract cancer

### Biomarkers

> Patients with biliary tract cancer need to be molecularly profiled up front, and it is a very exciting time now with the ongoing identification of

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