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EA2165: A Randomized Phase II Study of Nivolumab After Combined Modality Therapy (CMT) in High Risk Anal Cancer
PI: Olatunji Alese, MD
**Cholangio and/or Gall Bladder**

**1st line Therapy**

- **UMCC 2017.026A (CA209-9FC):** Multi-Center Randomized Phase II Study of Nivolumab in Combination with Gemcitabine/Cisplatin or Ipilimumab as First Line Therapy for Patients with Advanced Unresectable Biliary Tract Cancer
  - **PI:** Walid Shaib, MD

**Phase 2**

- **ARQ 087 (DZB-CS-301):** A pivotal study of Derazantinib in patients with inoperable or advanced inoperable intrahepatic cholangiocarcinoma and FGFR2 gene fusions or FGFR2 gene mutations or amplifications
  - **PI:** Walid Shaib, MD

- **WCI4468:** Evaluation of the Effect of 2 vs. 6 Hour Oxaliplatin Infusions on Neuropathy and Pharmacokinetics in Patients with Gastrointestinal Cancers
  - **PI:** R. Donald Harvey, PharmD

**Phase 2A**

- **ABC-108:** A Phase IIA Study of ABC294640 (Yeliva®) in the Treatment of Patients with Advanced, Unresectable Intra-hepatic, Perihilar and Extra-Hepatic Cholangiocarcinoma
  - **PI:** Mehment Akce MD

- **WCI4146:** A Study of Trifluridine/Tipiracil (TAS102) in Combination with Nanoliposomal Irinotecan (NAL-IRI) in advanced GI cancers
  - **PI:** Olatunji Alese, MD

**Phase 1/2**

- **ACCRU-GI-1603:** Irinotecan Liposome(nal-IRI), Fluorouracil, Leucovorin and Reucaparib in the Treatment of Select Gastrointestinal Metastatic Malignancies Followed by a Phase II Study of First line treatment of Selected Patients with Metastatic Adenocarcinoma of the Pancreas with Genomic Markers (Signature) of Homologous Recombination Deficiency (HRD)
  - **PI:** Christina Wu, MD
EU4339-18, A Single-arm Feasibility Study of Gemcitabine, Cisplatin, and Nab-Paclitaxel as Neoadjuvant Therapy for Resectable Oncologically High-Risk Intrahepatic Cholangiocarcinoma  
PI: Shishir Maithel, MD

EU4338-18: Perioperative Chemotherapy Prior to and After Reoperation for Incidental Gallbladder Cancer - An International, Randomized Phase III Trial  
PI: Shishir Maithel, MD

WCI4173, Effects on QOL when Zinc is replaced in Patients with Upper GI Cancer on Chemotherapy  
PI: Edith Brutcher
### Colorectal

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PI: Christina Wu, MD |
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PI: Bassel El-Rayes, MD

EA2142, Randomized Phase II Study of Platinum and Etoposide versus Temozolomide and Capecitabine in Patients with Advanced G3 Non-Small Cell Gastroenteropancreatic Neuroendocrine Carcinomas
PI: Walid Shaib, MD
Liver

**Adjuvant Therapy**

- **Phase 3**
  - CA209-9DX, A Randomized, Double-blind Study of Adjuvant Nivolumab versus Placebo for Participants with Hepatocellular Carcinoma Who Are at High Risk of Recurrence after Curative Hepatic Resection or Ablation (CheckMate 9DX)  
    PI: Mehmet Akce, MD

**Treatment for advanced disease**

- **Phase 3**
  - MK-7902-002-01 A Multicenter, Randomized, Double-blinded, Active-controlled, Clinical Study to Evaluate the Safety and Efficacy of Lenvatinib (E7080/MK-7902) in Combination with Pembrolizumab (MK-3475) Versus Lenvatinib in First-line Therapy of Participants with Advanced Hepatocellular Carcinoma (LEAP-002)  
    PI: Mehmet Akce, MD

- **Phase 1/2**
  - POLARIS2013-001, Study of ADI-PEG 20 plus FOLFOX in Subjects with Advanced Gastrointestinal Malignancies Focusing on Hepatocellular Carcinoma  
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PI: Edith Brutcher
EA2165: A Randomized Phase II Study of Nivolumab After Combined Modality Therapy (CMT) in High Risk Anal Cancer
PI: Olatunji Alese, MD

**Inclusion**
- No prior chemotherapy/XRT for anal cancer → Arm T
- Prior chemotherapy/XRT → Arm S
- Patient with HIV + are permitted. Pt with CD4>200 and serum HIV viral load <200 copies/mm³ are eligible.
- Pt must have received ≥ 54 Gy of XRT to the PTVp and 45 Gy to PTVn
- ECOG PS 0~2

**Exclusion**
- Prior treatment with an immune checkpoint inhibitor
- Concurrent malignancy unless disease-free for ≥ 2 years
- Symptomatic Interstitial lung disease
- Autoimmune disease required systemic treatment in past 2 years
UMCC 2017.026A (CA209-9FC): Multi-Center Randomized Phase II Study of Nivolumab in Combination with Gemcitabine/Cisplatin or Ipilimumab as First Line Therapy for Patients with Advanced Unresectable Biliary Tract Cancer
PI: Walid Shaib, MD

**Inclusion**
- Adenocarcinoma of the biliary tract that is not eligible for curative resection, transplantation or ablative therapies
- No prior systemic therapy for advanced BTC
- Prior Adj chemotherapy > 6 months is permitted
- Prior Radiation, chemo or Radioembolization or other local ablative therapies or hepatic resection is permitted >= 4 weeks
- Child-Pugh score of A
- No known Hepatitis B, C or HIV seropositivity

**Exclusion**
- Active second malignancy other than non-melanoma skin cancer or cervical carcinoma
- Ongoing active, uncontrolled infections
- Active, Known or suspected autoimmune disease
- Prior Radiation, chemo or Radioembolization or other local ablative therapies or hepatic resection is permitted >= 4 weeks
ARQ 087 (DZB-CS-301): A pivotal study of Derazantinib in patients with inoperable or advanced intrahepatic cholangiocarcinoma and FGFR2 gene fusions or FGFR2 gene mutations or amplifications  
PI: Walid Shaib, MD

- FGFR2 gene fusion confirmed by FISH (central lab) or either FISH or NGS (local lab) followed by confirmation from central lab  
- Progression after at least one regimen of systemic therapy or not tolerated prior systemic therapy.

- Systemic therapy, major surgery, locoregional therapy or XRT < 4 weeks  
- Previous anti-FGFR inhibitor therapy  
- Clinically unstable brain metastases (eligible if stable ≥ 3 months  
- Current evidence of Corneal or retinal disorder  
- Concurrent uncontrolled or active hepatobiliary disorders  
- History of significant cardiac disorders

ABC-108: A Phase IIA Study of ABC294640 (Yeliva®) in the Treatment of Patients with Advanced, Unresectable Intra-hepatic, Perihilar and Extra-Hepatic Cholangiocarcinoma  
PI: Mehment Akce MD

- No more than 2 prior treatment for advanced or metastatic CCA.  
- Previous systemic therapies for early stage disease are not considered as part of the 2 allowed therapy  
- The tumor is unresectable and not amenable to curative therapy.

- >2 previous systemic anti-neoplastic regimens for advanced/metastatic CCA  
- Active, uncontrolled infections, requiring systemic therapy.  
- Known infection with human immunodeficiency virus.  
- Serious nonmalignant disease that could compromise protocol objectives in the opinion of the investigator and/or the sponsor.
Neoadjuvant/ Perioperative Therapy

**EU4339-18**, A Single-arm Feasibility Study of Gemcitabine, Cisplatin, and Nab-Paclitaxel as Neoadjuvant Therapy for Resectable Oncologically High-Risk Intrahepatic Cholangiocarcinoma

**PI:** Shishir Maithel, MD

- Intrahepatic Cholangiocarcinoma
- Resectable but High Risk,

- T-stage ≥ IB (IB –IV)
- Solitary Lesion > 5 cm
- Mulifocal tumors or satellite lesions present confined to the same lobe as the dominant lesion but still resectable
- Major vascular invasion but resectable
- Suspicious or involved regional lymph node N1

- Distant extrahepatic disease
- Peripheral neuropathy ≥ Grade 2
- Concurrent severe and/or uncontrolled medical condition
- Known CNS disease, except for treated brain metastasis
- No previous (≤ 5 years) or concurrent presence of other cancer except non-melanoma skin cancer and in situ carcinoma

**EU4338-18**: Perioperative Chemotherapy Prior to and After Reoperation for Incidental Gallbladder Cancer – An International, Randomized Phase III Trial

**PI:** Shishir Maithel, MD

- Gallbladder cancer discovered incidentally at the time of or following routine cholecystectomy for presumed benign disease
- Resectable disease
- Enrollment and randomization within 12 weeks after initial cholecystectomy

- Presence of active infection
- Known dihydropyrimidine dehydorgenase deficiency

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**Treatment for advanced or metastatic disease**

**Colorectal**

**Inclusion**

- Prior treatment w/ 5FU, Oxaliplatin and Irinotecan
- Treat with anti-EGFR if extended RAS wt
- Stable DM treatment for Pt w/ Diabetes Milieus

**Exclusion**

- Metformin use in the last 3 months
- Prior PD-1, PD-L1 ImmunoTx

**WCI4494, Nivolumab and Metformin in patients with treatment refractory MSS metastatic Colorectal Cancer**

PI: Mehmet Akce, MD
ACCRU-GI-1617, (MOUNTAINEER): A Phase II, Open Label Study of Tucatinib Combined with Trastuzumab in Patients with HER2+
Metastatic Colorectal Cancer

PI: Christina Wu, MD

- Subjects must have been treated with a fluoropyrimidine, oxaliplatin, irinotecan, an anti-VEGF monoclonal antibody, and an anti-PD-1 monoclonal antibody if tumor has deficient mismatch repair proteins or is MSI-High, or contraindication to such treatment(s).
- HER2(ERBB) over-expression
- RAS (KRAS and NRAS) wild-type

Prior anti-HER2 targeting therapy
Stage IV colorectal adenocarcinoma

- Liver metastasis confirmed to be surgically resectable, with surgery evaluation and planned resection. May have minimal extrahepatic disease that is determined to be resectable.
- Microsatellite stable (MSS).

Prior PD-1, PD-L1 ImmunoTx
- Uncontrolled intercurrent illness

PI: Christina Wu, MD
S0820 A double blind placebo-controlled trial of eflornithine and sulindac to prevent recurrence of high risk adenomas and second primary colorectal cancers in patients with stage 0-III colon or rectal cancer (PACES)
PI: Mehmet Akce, MD

Stage 0, I, II or III colon or rectal adenocarcinoma

- Treated w/ Resection alone or in combination w/ RT or Chemo
- Primary Resection in between 180 days and 456 days (inclusive)
- Patients must show no evidence of disease (NED) based on post-operative colonoscopy and CT C/A/P (for high risk pt)

Pathology
Inclusion
Exclusion

- Patients must not have a known history of familial adenomatous polyposis, hereditary nonpolyposis colorectal cancer, or inflammatory bowel disease.
- Patients with hearing loss >40 dB
- No other prior malignancy is allowed except for adequately treated basal cell or squamous cell skin cancer, in situ cervical cancer, or other cancer for which the patient has been disease-free for > 5 years.
Treatment for advanced or metastatic disease

**WCI4468, Evaluation of the Effect of 2 vs. 6 Hour Oxaliplatin Infusions on Neuropathy and Pharmacokinetics in Patients with Gastrointestinal Cancers**

PI: R. Donald Harvey, PharmD

- Confirmed Gastrointestinal Cancer
  - Plan for ≥ 4 cycles Chemo w/ FOLFOX containing Therapy
  - Adequate bone marrow, liver and renal functions

- Exclusion
  - Grade 2 or higher peripheral neuropathy
  - Patient currently on cancer therapies or have received cancer therapies within 4 weeks of the start of FOLFOX6
  - Sever or uncontrolled medical conditions
  - History of severe hemorrhage
**WCI4146: A Study of Trifluridine/Tipiracil (TAS102) in Combination with Nanoliposomal Irinotecan (NAL-IRI) in advanced GI cancers**

**PI:** Olatunji Alese, MD

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**Treatment for Advanced Disease**

- **Inclusion**
  - Failed at least one prior therapy for advanced or metastatic disease
  - Prior therapy with Irinotecan (Phase 2 only)
  - Known active additional malignancy
  - Known active CNS metastases and/or carcinomatous meningitis
  - Known history of HIV
  - Homozygous for UGT1A1*28 allele (phase I)

- **Exclusion**
  - Stage IV or locally advanced unresectable GI adenocarcinomas
  - Known or active CNS metastases and/or carcinomatous meningitis
  - Known history of HIV
  - Homozygous for UGT1A1*28 allele (phase I)

**Pathology**

- Phase I: Gastric, Cholangiocarcinoma, Pancreatic, Colorectal
- Phase 2: Pancreatic and colorectal cancer
Winship3321-16: Trial of pembrolizumab and XL888 in patients with advanced gastrointestinal malignancies

PI: Bassel El-Rayes, MD

**Stage IV or locally advanced unresectable GI cancer**

- Failed at least one prior therapy for advanced or metastatic disease
- Patients with colorectal cancer must have previously received oxaliplatin, irinotecan, and a fluoropyrimidine therapy

**Inclusion**

- Any cancer treatment within 4 weeks of D1
- Known history of active TB
- Prior PD-1, PD-L1, PD-L2 or HSP inhibitor
- Known history of HIV
- Known active Hepatitis B or Hepatitis C

**Exclusion**

- Failed at least one prior therapy for advanced or metastatic disease
- Patients with colorectal cancer must have previously received oxaliplatin, irinotecan, and a fluoropyrimidine therapy

**Pathology**

- Pancreatic
- GI
- Colorectal
ACCRU-GI-1603, Irinotecan Liposome(nal-IRI), Fluorouracil, Leucovorin and Reucaparib in the Treatment of Select Gastrointestinal Metastatic Malignancies Followed by a Phase II Study of First line treatment of Selected Patients with Metastatic Adenocarcinoma of the Pancreas with Genomic Markers (Signature) of Homologous Recombination Deficiency (HRD)
PI: Christina Wu, MD

Phase I:
- Metastatic pancreatic cancer: ≤ 2 lines of prior therapy metastatic setting
- Metastatic colorectal cancer: ≤ 3 lines of prior therapy metastatic setting
- Metastatic gastroesophageal cancer: ≤ 1 lines of prior therapy metastatic setting
- Metastatic biliary cancer: ≤ 1 lines of prior therapy metastatic setting
  Phase 1b
- Metastatic pancreatic cancer: 1 lines of prior therapy metastatic setting
- Metastatic gastroesophageal cancer: 1 lines of prior therapy metastatic setting
  Phase II
Metastatic adenocarcinoma of the pancreas with genomic marker:
Homologous Recombination Deficiency(HDR): BRCA1/2 or PALB2 mutations or non-BRCA1, non-PALM HDR: not received any systemic therapy in the metastatic setting

- Co-morbid systemic or other severe concurrent disease
- Immunocompromised patients, known HIV positive
- Uncontrolled intercurrent illness
- Prior PARPi treatment
WCI4173, Effects on QOL when Zinc is replaced in Patients with Upper GI Cancer on Chemotherapy
PI: Edith Brutcher

Non-resectable gastric, gastro-esophageal, Pancreas or biliary cancer

- Patients plan to receive chemotherapy at an EMORY Cancer center
- No prior chemotherapy or XRT for newly diagnosed disease

Breast feeding or pregnant women
Treatment for advanced disease

**GIST & NET**

**XmAb18087-01, Multiple Dose Study to Evaluate the Safety and Tolerability of XmAb®18087 in Subjects with Advanced Neuroendocrine and Gastrointestinal Stromal Tumors (DUET-1)**

**PI:** Bassel El-Rayes, MD

- NET and GIST tumors must be unresectable
- NET subjects must have progressed within the past 12 months on or been ineligible for treatment with somatostatin analogues (SSA) and at least one other targeted therapy
- GIST subjects must have previously received all FDA-approved therapies

**Locally advanced or metastatic GIST**

**Unresectable, locally advanced or metastatic, well-differentiated low or intermediate grade NET of pancreatic, GI, Lung or undetermined origin.**

**EA2142, Randomized Phase II Study of Platinum and Etoposide versus Temozolomide and Capecitabine in Patients with Advanced G3 Non-Small Cell Gastroenteropancreatic Neuroendocrine Carcinomas**

**PI:** Walid Shaib, MD

- Locally advanced and unresectable or metastatic gastroenteropancreatic neuroendocrine carcinoma that is either known or suspected to be of GI origin.
- Pathologically/histologically confirmed tumor of non-small cell histology.
- Ki-67 proliferative index of 20-100% OR at least 10 mitotic figures per 10 high powered fields
- Patients may not have had any prior systemic treatment for this malignancy
- Patients may not have received any of the protocol agents within 5 years prior to randomization.

**• Prior treatment with an immune checkpoint inhibitor**
**• Concurrent malignancy unless disease-free for ≥ 2 years**
**• Symptomatic Interstitial lung disease**
**• Autoimmune disease required systemic treatment in past 2 years**

**• Primary tumors arising from the lung, gynecologic organs or prostate**
**• Patients may not be receiving Coumadin while on treatment**
**• Patients with brain metastases or presence of carcinomatous meningitis**
**• Patients with known DPD deficiency**
CA209-9DX, A Randomized, Double-blind Study of Adjuvant Nivolumab versus Placebo for Participants with Hepatocellular Carcinoma Who Are at High Risk of Recurrence after Curative Hepatic Resection or Ablation (CheckMate 9DX)
PI: Mehmet Akce, MD

**HCC (Hepatocellular Carcinoma)**
- HCC, curative intent by resection of local ablation
- HBV-HCC: (1) Resolved HBV infection, (2) Chronic HBV infection: on antiviral therapy and HBV DNA < 500 IU/mL
- HCV-HCC: (1) Resolved HCV infection as evidenced by detectable antibody, OR (2) Chronic HCV infection as evidenced by detectable HCV RNA.

**Pathology**
- Hepatic Resection up to three tumors, at least one tumor ≥ 5 cm, no macrovascular invasion
- Non with ≥ 5 cm, with microvascular invasion or Poorly/undifferentiated HCC (G3,G4)
- More than 3 tumors with no evidence of macrovascular invasion
- Local ablation with solitary tumor > 3 cm or ≤ 5 cm or multiple tumors (up to 4) none with > 5 cm

**Inclusion**
- Known fibrolamellar HCC, Sacromatoid HCC, mixed cholangiocarcinoma/HCC
- Prior recurrence of HCC
- Any evidence of tumor metastasis or concurrent malignant disease
- No active co-infection with Hepatitis B and C, Hepatitis D and B
- Known history of HIV positive or AIDS
- Active, known or suspected autoimmune disease

**Exclusion**
Liver

**Inclusion**
- Radiographic evidence of cirrhosis
- Liver mass showed arterial phase hyperenhancement on triphasic CT or MRI and either ≥ 20mm with either non-peripheral portal washout or enhancing capsule or 10-19 mm with non-peripheral portal venous washout and an enhancing capsule
- Have BCLC stage C or stage B disease not amendable to locoregional therapy or refractory to locoregional therapy and not amendable to a curative treatment

**Exclusion**
- Fibrolamella and mixed HCC/Cholangiocarcinoma subtype
- Has had esophageal or gastric variceal bleeding within the last 6 months
- Not controlled ascites
- Portal vein invasion, inferior vena cava cardiac involvement of HCC
- Have received any systemic therapy, including anti-VEGF therapy, or any systemic investigational anticancer agents for advanced/unresectable HCC
- Prior anti-PD_1, anti-PD-L1 or anti-PD-L2 or with an agent targeting T-cell receptor
- Locoregional therapy to live
- Dual active HBV and HCV infection
- Active Tuberculosis

**Pathology**
- Treatment for advanced disease
- Advanced histologically or cytologically proven HCC
- Treatment with at least 2 prior systemic therapy regimens
- Brain metastases are allowed if well controlled and without seizures.
- Subjects with active hepatitis B or C on anti-viremic compounds may remain on such treatment, except for interferon.

**Treatment for advanced disease**
- MK-7902-002-01 A Multicenter, Randomized, Double-blinded, Active-controlled, Clinical Study to Evaluate the Safety and Efficacy of Lenvatinib (E7080/MK-7902) in Combination with Pembrolizumab (MK-3475) Versus Lenvatinib in First-line Therapy of Participants with Advanced Hepatocellular Carcinoma (LEAP-002) PI: Mehmet Akce, MD
- POLARIS2013-001, Study of ADI-PEG 20 plus FOLFOX in Subjects with Advanced Gastrointestinal Malignancies Focusing on Hepatocellular Carcinoma PI: Mehmet Akce MD
Pancreatic Adenocarcinoma

Cohort 1: Subjects must not have received systemic therapy for metastatic pancreatic adenocarcinoma.

Cohort 2: Subjects must have received and radiologically progressed on only 1 prior line of systemic therapy for metastatic pancreatic adenocarcinoma. This must have been a gemcitabine-based regimen.

Prior receipt of any immune-mediated therapy including, but not limited to, other anti-CTLA-4, anti-PD-1, anti-PD-L1 antibodies and agents targeting CD73, CD39, or adenosine receptors, excluding therapeutic anticancer vaccines.

Subjects with a history of venous thrombosis within the past 3 months.

Subjects with prior history of myocardial infarction, transient ischemic attack, or stroke within the past 3 months.

Other invasive malignancy within 2 years.

CT 4006, A Randomized Controlled, Open label, Adaptive Phase-3 Trial to Evaluate Safety and Efficacy of EndoTAG-1 Plus Gemcitabine versus Gemcitabine alone in Patients with Measurable Locally Advanced and/or Metastatic Adenocarcinoma of the Pancreas Failed on FOLFIRINOX Treatment

PI: Olatunji Alese, MD

Metastatic or locally advanced disease that is considered unresectable.

Documented disease progression on first line FOLFIRINOX.

Significant active/unstable non-malignant disease likely to interfere with study assessments.

Any anti-tumor treatment (except FOLFIRINOX as the first-line therapy) for pancreatic adenocarcinoma before enrollment.

Any radiotherapy for pancreatic adenocarcinoma before enrollment except for treatment of bone metastases if target lesions are not included in the irradiated field.
HCRN GI14-198: Randomized, Double-Blind Study of mFOLFIRINOX plus Ramucirumab versus mFOLFIRINOX plus placebo in Advanced Pancreatic Cancer Patients
PI: Bassel El-Rayes, MD

**1st Line Metastatic Disease**

**Pathology**

**Pancreatic**

**Inclusion**

- No prior first line systemic treatment (prior adjuvant or neoadjuvant treatment is permitted).
- Subjects whose disease has progressed after 6 months of last systemic chemotherapy or chemo-radiation in the adjuvant or neoadjuvant setting are eligible.

**Exclusion**

- Ongoing or active infection
- Uncontrolled or poorly-controlled hypertension
- Cirrhosis at a level of Child-Pugh B (or worse) or cirrhosis (any degree) with a history of hepatic encephalopathy or clinical meaningful ascites resulting from cirrhosis;
- History of deep vein thrombosis, pulmonary embolism, or any other significant thromboembolism (venous port or catheter thrombosis or superficial venous thrombosis are not considered “significant”) during the 3 months prior to randomization.
- Concurrent active malignancy
WCI4441: Weight Loss in Patients with Advanced Stage Pancreatic Cancer: Role of Serotonin and Effects of Telotristat Ethyl
PI: Edith Brutcher

### Inclusion
- Subject present for first line chemotherapy treatment for metastatic disease.
- Prior systemic therapy (adjuvant or neoadjuvant setting are acceptable) if disease progressed or recurred within at least 3 months after treatment.
- Group 1: weight loss of 10% or more
- Group 2: Stable weight or loss of < 10% by history

### Exclusion
- Subjects with histology other than adenocarcinoma;
- Concurrent active malignancy

Advanced stage pancreas cancer (locally advanced unresectable, recurrent/metastatic)
**Neoadjuvant/advanced disease therapy**

**Pancreatic**

**Stage I-III pancreatic adenocarcinoma**
- Cancer confirmed to be surgically resectable, with surgery evaluation with planned resection.
- Patients may have prior neoadjuvant chemotherapy, but no neoadjuvant chemoradiation.

**Inclusion**

**Exclusion**
- No neoadjuvant chemoradiation
- Uncontrolled intercurrent illness

**WCI4142: Integrated biomarker trial of VX15/2503 in combination with ipilimumab or nivolumab in patients with pancreatic and colorectal cancer**

PI: Christina Wu, MD
Distal pancreatectomy, minimally invasive or open, for malignancy (DIPLOMA): a randomized controlled, multicenter, non-inferiority trial.

PI: Mihir Shah M.D.

**Inclusion**
- Resectable biopsy proven or suspected PDAC in the pancreatic body or tail
- Upfront (without induction / down-sizing radio- or chemotherapy) resectable PDAC in the pancreatic body or tail
- Elective indication for distal pancreatectomy for proven or suspected PDAC

**Exclusion**
- ASA >3
- A medical history of chronic pancreatitis (according to the MANNHEIM criteria)
- Second malignancy necessitating resection during the same procedure.
- Radiotherapy because of pancreatic cancer prior to distal pancreatectomy.
- Distant metastases (M1) including involved distant lymph nodes
- Tumor involvement or abutment of major vessels