GI CLINICAL TRIALS

Laura Tenner MD MPH

DISCLOSURES

- Nothing to disclose


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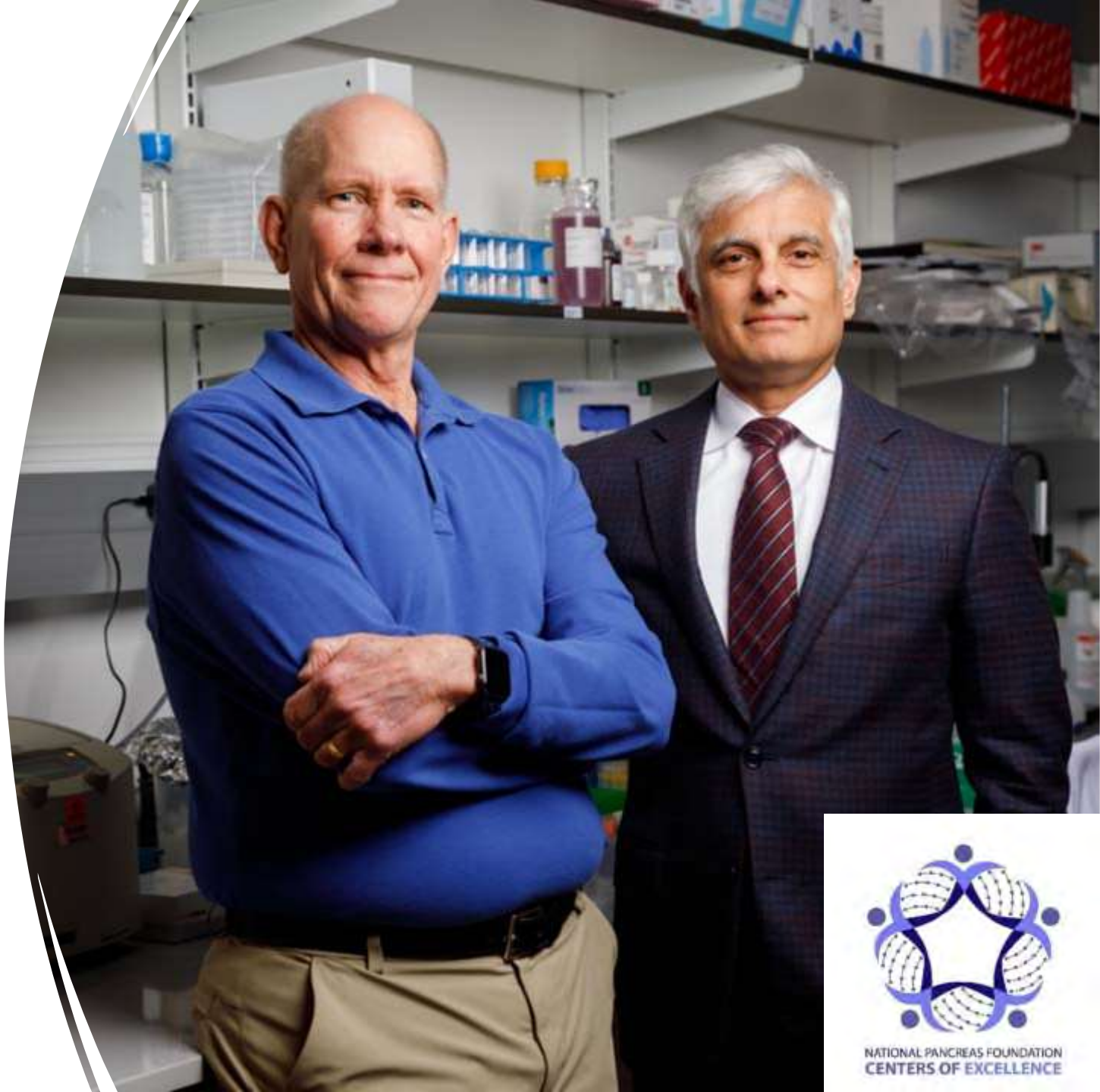
PANCREATIC CANCER

Sunil Hingorani, MD, PhD, the Nancy Armitage Pancreas Cancer Clinical Research Presidential Chair and Director of the Pancreatic Cancer Center of Excellence at UNMC.



NATIONAL PANCREAS FOUNDATION
CENTERS OF EXCELLENCE

PANCREATIC TRIALS

- RINTATOLIMOD (AMPLIGEN) COMPARED TO NO TREATMENT FOLLIWNG FOLIFINOX IN SUBJECTS WITH LOCALLY ADVANCED PANCREATIC ADENOCARCINOMA
  - NCT 05494697
  - PHASE 2, RANDOMIZED, OPEN-LABEL CONTROLLED STUDY TO EVALUATE THE EFFICACY AND SAFETY OF AMPLIGEN TREATMENT COMPARED TO A CONTROL GROUP (NO TREATMENT) FOLLOWING FOLFIRINOX TREATMENT IN LOCALL ADVANCED PANCREATIC ADENOCARCINOMA
  - ONLY IN NEBRASKA AND OHIO

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PANCREATIC TRIALS

- NCT 05494697
- SUBJECTS WILL RECEIVE RINTATOLIMOD IV UP TO 400MG TWICE WEEKLY UNTIL DISEASE PROGRESSION; CONTROL GROUP IS NO TREATMENT
- PRIMARY OUTCOME: PROGRESSION FREE SURVIVAL (PFS)
- SECONDARY OUTCOMES: OVERALL SURVIVAL (OS), OBJECTIVE RESPONSE RATE (ORR), DURATION OF RESPONSE DOR)

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PANCREATIC TRIALS

- NCT 05494697
- RINTATOLIMOD (TLR-3 AGONIST) MAY IMPROVE PANCREATIC CANCER PATIENTS' SURVIVAL VIA IMMUNOMODULATION
- SINGLE INSTITUTION STUDY SHOWED B-CELLS WERE SIGNIFICANTLY INCREASED IN PATIENTS TREATED WITH RINTATOLIMOD WITH LONG TERM SURVIVAL
- MEDIAN PFS WAS 13 MONTHS WITH RINTATOLIMOD VERSUS 8.6 MONTHS IN A SUBSET OF MATCHED CONTROLS

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El Haddaoui H, Brood R, Latifi D, Oostvogels AA, Klaver Y, Moskie M, Mustafa DA, Debets R, van Eijck CHJ. Rintatolimod (Ampligen(R)) Enhances Numbers of Peripheral B Cells and Is Associated with Longer Survival in Patients with Locally Advanced and Metastasized Pancreatic Cancer Pre-Treated with FOLFIRINOX: A Single-Center Named Patient Program. Cancers (Basel). 2022 Mar 8;14(6):1377. doi: 10.3390/cancers14061377

PANCREATIC TRIALS

- HYPOFRACTIONATED STEREOTACTIC BODY RADIATION THERAPY AND FLUOROURACIL OR CAPECITABINE WITH OR WITHOUT ZOLEDRONIC ACID IN TREATING PATIENTS WITH LOCALLY ADVANCED PANCREATIC CANCER
- NCT 03073785
- PHASE 2 TRIAL STUDIES HOW WELL HYPORACTIONATED STEROTACTIC BODY RADIATION THERAPY AND FLUOROURACIL OR CAPECITABINE WITH OR WITHOUT ZOLEDRONIC ACID WORK IN TREATING PATIENTS WITH PANCREATIC CANCER THAT HAS SPREAD FROM WHERE IT STARTED TO NEARBY TISSUE OR LYMPH NODES.
- ONLY AT UNMC

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PANCREATIC TRIALS

- CONTROL: Patients undergo hypofractionated stereotactic body radiation therapy in 5 fractions on days 1-5. Patients receive fluorouracil IV over 24 hours on day 1 weekly for 4 weeks or capecitabine PO every 12 hours starting the evening before day 1 of radiation therapy for 4 weeks as per standard of care. Patients then undergo surgery 6-8 weeks after completion of radiation therapy.
- Experimental: Arm B (zoledronic acid, chemotherapy, radiation therapy)Patients receive zoledronic acid IV over no less than 15 minutes 1 week prior to radiation therapy. Patients undergo hypofractionated stereotactic body radiation therapy and receive treatment with fluorouracil IV or capecitabine PO as in Arm A. Patients then undergo surgery 6-8 weeks after completion of radiation therapy.

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PANCREATIC TRIALS

- PRIMARY ENDPOINT: LOCAL CONTROL
- SECNDARY ENDPOINT:
  - MAXIMUM TOLERATED DOSE OF ZOLEDRONIC ACID
  - LOCAL FALURE-FREE SURVIVOAL
  - OVERALL SURVIVAL
  - SURGICAL COMPLETE RESECTION RATE
  - PATHOLOGIC RESPONSE
  - CHANGE OF TUMOR SIZE AND SUV

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BILIARY TRACT CANCER AND PANCREATIC CANCER

BILIARY TRACT CANCER/PANCREATIC CANCER

- PALLIADELIC TREATMENT TO REDUCE PSYCHOLOGICAL DISTESS IN PERSONS WITH INOPERABLE PANCREATOBILIARY CANCER
- NCT 05220046
- An Exploratory Pilot Study of Palliadelic Treatment to Reduce Psychological Distress and Improve Quality of Life in Persons With Pancreatobiliary Cancer, With a Parallel Assessment of Healthcare Utilization and Family Wellbeing
- ONLY AT UNMC

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BILIARY TRACT CANCER/PANCREATIC CANCER

- Experimental: Psilocybin Treatment Arm--Participant with pancreatobilliary cancer will receive 25mg of psilocybin in one 8-hour monitored session with supportive counseling before and after session. Integration sessions (2-3 sessions lasting up to 90 minutes each) will take place in the outpatient palliative care clinic or by phone or tele-heath. Primary and secondary objectives are complete at one-week post treatment, longitudinal exploratory measures collected up to 12 months post baseline.
- No Intervention: Family Observation Group--The study participant will select a family member who will provide parallel data regarding distress related to pancreatobiliary cancer.

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BILIARY TRACT CANCER/PANCREATIC CANCER

- PRIMARY OUTCOME: RECRUITMENT AND RENTENTION RATES
- SECONDARY OUTCOMES: PHQ-9, GAD-7, D-II

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HCC

HEPATOCELLULAR CARCINOMA

- **A STUDY OF ATEZOLIZUMAB AND BEVACIZUMAB IN HEPATOCELLULAR CARCINOMA (AB7)**
- This is a nonrandomized, single arm feasibility study with the primary goal of evaluating the safety profile of the combination of atezolizumab and bevacizumab in patients with advanced/metastatic HCC with Child-Pugh B7 and B8 liver disease who have received no prior systemic therapy.
- Multiple Institutions: Texas, Wisconsin, New York, New Jersey, Indiana, Illinois as well as here

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For More Info: Mridula.Krishnan@unmc.edu

HEPATOCELLULAR CARCINOMA

- Experimental Study Treatment: Atezolizumab 1,200 mg IV and bevacizumab 15 mg/kg IV every 3 weeks (on day 1 of each 21-day cycle).
- Treatment will continue until disease progression or development of unacceptable toxicity.
- Primary Outcome: Disease toxicity
- Secondary Outcome: Overall Response Rate, Disease Control Rate, Duration of Response, Median Progression Free Survival, Median Overall Survival

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RECTAL CANCER

RECTAL CANCER

- **TRIAL OF THE EFFICACY AND SAFETY OF SHORT AND LONG COURSE RADIATION THERAPY WITH/WITHOUT BMX-001**
- NCT 05254327
- In this Phase 2 study, we will conduct an efficacy and safety study of the combination of investigational drug BMX-001, with short-course radiotherapy (SCRT) or long-course chemoradiotherapy (LCCRT) as part of total neoadjuvant therapy in newly diagnosed rectal adenocarcinoma (RAC) patients.
- Only at UNMC

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RECTAL CANCER

- Cohort 1: Long Course Chemo-radiation (LCCRT) cohort..
- Cohort 2: The Randomized Short Course Radiation (SCRT) cohort.
- All patients in the trial will receive BMX-001 (A loading dose of 28 mg/subject followed by maintenance doses of 14 mg/subject twice a week) with either SCRT or LCCRT.
- Cohort 1 and 2 will begin enrolling concurrently.

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RECTAL CANCER

- Primary Outcome: Toxicity (GI, GU, Skin, hematologic) grade 3 and above

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COLON CANCER

COLON CANCER

- **TESTING THE ADDITION OF TOTAL ABLATIVE THERAPY TO USUAL SYSTEMIC THERAPY TREATMENT FOR LIMITED METASTATIC COLORECTAL CANCER, THE ERASUR STUDY**
- This phase III trial compares total ablative therapy and usual systemic therapy to usual systemic therapy alone in treating patients with colorectal cancer that has spread to up to 4 body sites (limited metastatic).
- Occurring multiple sites across the US

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COLON CANCER

- OUTLINE: Patients are randomized to 1 of 2 arms.
- ARM 1: Patients undergo Total Ablative Therapy on study, consisting of stereotactic ablative radiotherapy with or without surgical resection and/or microwave ablation. Patients also receive standard of care chemotherapy on study.
- ARM 2: Patients receive standard of care chemotherapy on study.

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COLON CANCER

- PRIMARY OBJECTIVE: To evaluate and compare overall survival (OS) (measured from time of randomization) in patients with newly diagnosed oligometastatic colorectal cancer (oCRC) treated with total ablative therapy (TAT) in addition to standard of care (SOC) systemic therapy versus SOC systemic therapy.
- SECONDARY OBJECTIVES:
  - I. To evaluate and compare event-free survival (EFS) (measured from time of randomization) between the two treatment arms.
  - II. To assess the adverse events (AE) profile within each of the two treatment arms.
  - III. To evaluate the time to local recurrence (TLR) (measured from completion of TAT) in patients with newly diagnosed oCRC treated with TAT + SOC systemic therapy.

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ANAL CANCER

ANAL CANCER

- **EA2176: PHASE 3 CLINICAL TRIAL OF CARBOPLATIN AND PACLITAXEL +/- NIVOLUMAB IN METASTATIC ANAL CANCER PATIENTS**
- This phase 3 trial compares the addition of nivolumab to chemotherapy (carboplatin and paclitaxel) versus usual treatment (chemotherapy alone) for the treatment of anal cancer that has spread to other places in the body (metastatic).
- Multi-site all over the US

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ANAL CANCER

- OUTLINE: Patients are randomized to 1 of 2 arms. Randomization will be 2:1 favoring Arm B.
- ARM A: Patients receive paclitaxel intravenously (IV) on days 1, 8, and 15 of each cycle, and carboplatin IV on day 1 of each cycle. Treatment repeats every 28 days for up to 6 cycles in the absence of disease progression or unacceptable toxicity.
- ARM B: Patients receive nivolumab IV over 30 minutes on days 1 and 15 of cycle 1 and then on day 1 only of subsequent cycles, paclitaxel IV on days 1, 8, and 15 of each cycle, and carboplatin on day 1 of each cycle. Treatment repeats every 28 days for up to 6 cycles for carboplatin and paclitaxel, and up to 2 years for nivolumab in the absence of disease progression or unacceptable toxicity.
- After completion of study treatment, patients are followed up at 1 month, then every 3 months for 2 years.

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ANAL CANCER

- PRIMARY OBJECTIVE: To demonstrate that anti-PD-1 therapy in combination with carboplatin/weekly paclitaxel results in improved progression-free survival (PFS) versus systemic chemotherapy alone.
- SECONDARY OBJECTIVES:
  - I. To demonstrate that anti-PD-1 therapy in combination with carboplatin/weekly paclitaxel results in improved overall survival (OS) versus systemic chemotherapy alone.
  - II. To demonstrate that anti-PD-1 therapy in combination with carboplatin/weekly paclitaxel results in improved objective response using Response Evaluation Criteria in Solid Tumors (RECIST) version (v)1.1 versus systemic chemotherapy alone.
  - III. To evaluate toxicity profiles of the two regimens.

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THANK YOU

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