Clinical Trials: What's On The Horizon

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DISCLOSURES

- Consultant – Martell Diagnostics
- Grant Support – NIH/NCI
- Clinical Trial Support – Boehringer Ingleheim, Fusion Pharmaceuticals

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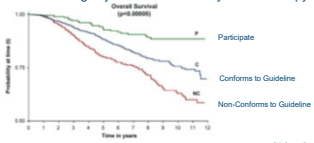
WHY CLINICAL TRIALS?

- All standard-of-care cancer therapy is based on results of clinical trials
- Patient participation in clinical trials improves outcomes – even when assigned to the control arm[1]
- Patients who participate in clinical trials view their care more positively than those who do not[2]

Quebec Tumor Registry – Breast Cancer Systemic Therapy



[1]Hebert-Croteau, et al. Breast Cancer Res Treat 91:279 2005 PMID: 15952061
[2]Julian-Reynier, et al. J Clin Oncol 25:3038 2007 PMID: 17536083

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BARRIERS TO PARTICIPATION

- Adult participation in cancer clinical trials ~5%[1]
- From NCI Director's Annual Report FY23[2]
  - Expand the use of telemedicine in clinical trials to reach patients where they live
  - Increase trial access for minority and underserved communities
  - Incorporate new enrollment and data collection approaches using modern, digital technology
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  - Increasing eligibility and reducing costs
  - Determine more quickly if a new intervention provides benefits to patients

[1]Unger, et al. Am Soc Clin Oncol Educ Book 35:185 2016 PMID: 27249699
[2]https://www.cancer.gov/research/annual-plan/scientific-topics/clinical-trials

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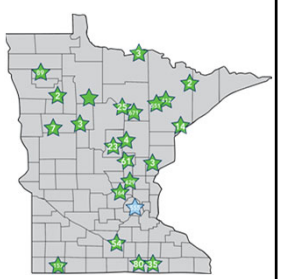
MN Cancer Clinical Trials Network

To improve cancer outcomes for all Minnesotans through greater access to cancer clinical trials in prevention and treatment



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MN Cancer Clinical Trials Network

HEALTH FAIRVIEW
SANFORD RESEARCH
THE HORMEL INSTITUTE UNIVERSITY OF MINNESOTA · MAYO CLINIC
metro-minnesota MMCORC community oncology research consortium
MAYO CLINIC Cancer Center
Essentia Health
MAYO CLINIC HEALTH SYSTEM
Masonic Cancer Center UNIVERSITY OF MINNESOTA
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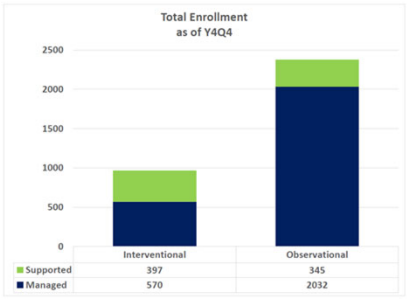
MNCCTN Enrollment

Total Enrollment in the first 4 years:

3,344



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MN CCTN Investigator Initiated Trials

- All partners have opportunity to propose trials
- Masonic Cancer Center resources can be help with trial design – biostatistical approach
- Observational trials that will lead to an interventional trial are appropriate
- Pilot funding made available for members

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Current IIT Trials

Study Name	PI Name	Study Sponsor	Clinical Research Category
Safely Stopping Pre-medications in Patients Receiving Paclitaxel A Randomized Phase III Trial	Michael Berger, PharmD and Maryam Lustberg, MD MPH	Ohio State University	Interventional
A Phase II Study to evaluate the safety of extending the routine flushing of implanted port devices from 4 weeks to 12 weeks: a Minnesota Cancer Clinical Trials Network (MNCCTN) Study	Bret Friday	Essentia Health	Interventional
Olanzapine for the Treatment of Chronic Nausea and/or Vomiting, Unrelated To Chemotherapy or Radiation, In Advanced Cancer Patients – A Confirmatory Phase III MNCCTN Trial	Charles Loprinzi, MD	Mayo Clinic Cancer Center	Interventional
Topical cannabidiol (CBD) for the treatment of chemotherapy-induced peripheral neuropathy a randomized placebo-controlled pilot trial	Stacy D'Andre, MD (Charles Loprinzi, Co-I)	Mayo Clinic Cancer Center	Interventional
QuitGuide App Aims 2 and 3	Dana Carroll	University of Minnesota	Observational
Implementation of proactive colon cancer screening program for the Native American community	Aasma Shaukat, MD, MPH	University of Minnesota	Interventional
QuitGuide App & American Indians: Aim 1	Dana Carroll	University of Minnesota	Observational
The Role of Cytomegalovirus and Inflammation on Patient Symptoms and Outcomes in Ovarian Cancer (CMV)	Rachel Vogel	University of Minnesota	Observational
Rose Geranium in Sesame Oil Nasal Spray as an Agent to Improve Symptoms of Nasal Vestibulitis: A Phase III Double Blinded Randomized Controlled Trial	Charles Loprinzi, MD	Mayo Clinic Cancer Center	Interventional
Laying the Foundation for Personalized Smoking Cessation Treatment in the American Indian Population: AIM 2	Dana Carroll	University of Minnesota	Observational

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Colchicine for the management of BRAF/MEK Inhibitor Associated Pyrexia

Jesus Vera Aguilera, MD | Essentia Health

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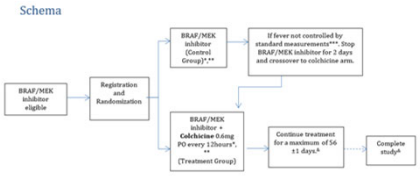
Schema



*Peripheral blood for CBC/CMP and cytokine levels at day 0, 28, 56±1 day (total 3 blood draws).
**Monitor temperature q12h in log and when concern for fever.
***www.ncbi.nlm.nih.gov/pmc/articles/PMC8482100/. See section 12 for standard management of pyrexia.
& Colchicine can be continued at physician discretion if clinical improvement is noted.
-BRAF/MEK inhibitor + colchicine can be given together at least 1 hour before or 2 hours after a meal.
-Control Group will receive no colchicine treatment, management of pyrexia will be per standard of care; if fever is not controlled, stop BRAF/MEK inhibitor for 2 days and crossover to colchicine arm (patients should have repeated blood work per *)

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Objectives

Primary Objectives

1. To determine the potential of colchicine in the prevention and treatment of pyrexia associated with BRAF/MEKi treatment.

Secondary Objectives

1. To examine the immunological changes in pyrogenic plasma cytokines and chemokines among patients who received BRAFi/MEKi that developed pyrexia.
2. To analyze cytokine profiles to serve as potential predictive biomarkers for fever development and severity.
3. To evaluate the potential implications of colchicine of peripheral blood mononuclear cells (PBMC) to determine the MAPK pathway.

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A Prospective, Randomized Study To Evaluate The Safety of Extending The Routine Flushing Of Implanted Port Devices From 4 Weeks To 12 Weeks

Bret Friday, MD | Essentia Health

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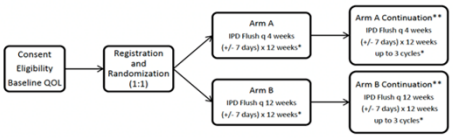
Schema



* 1 Cycle = 12 Weeks

** Continuation Arms are optional per patient consent

Stratification Factors: 1) IPD Age ≤ 2 years, No anticoagulant; 2) IPD Age ≤ 2 years, Anticoagulant; 3) IPD Age > 2 years, No anticoagulant; and 4) IPD Age > 2 years, Anticoagulant.

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Objectives

Primary Objectives

1. Estimate IPD patency rate with a planned 12-week flush interval as compared to an every 4-week flush interval

Secondary Objectives

1. valuate IPD patency rate during long term follow-up with planned 12 week versus 4 week intervals.
2. Identify differences in specific complications (occlusion, infection, mechanical) in 4 week versus 12 week interval.
3. Determine healthcare and patient cost difference between 4 week and 12 week IPD flushes.
4. Compare patient quality of life and satisfaction between study arms.
5. Evaluate impact of smoking, patient age, medical comorbidities, IPD age, and concomitant medications on complication rates.

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Exploring Future Research Ideas with MNCCTN

- Investigators can present research concepts at the Trial Review Committee meeting to get feedback before submitting a full application to the network
- This meeting is also open to anyone interested in research or learning more about the MNCCTN
- Please email Laurel Nightingale (nigh0021@umn.edu) if you would like to attend or present at an upcoming meeting

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Educational Campaign

GOAL
- Increasing knowledge of and comfort with clinical trials

TEAM
- Led by Minnesota Cancer Clinical Trials Network (MNCCTN)
- Advisory Committee of University, MNCCTN Partners, & stakeholders
- Community Consultants: paid ambassadors and experts who bring community interests and expertise to the campaign
- Agency bringing education & creative/marketing strategy and expertise

ABOUT
- Funded through MNCCTN state funding
- Contact: Jessie Alkire, Sr. Communications Specialist, jalkire@umn.edu or Susannah Bartlow, Community Outreach & Engagement Associate, bartl422@umn.edu

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July 2022-April 2023 Phase I: Discovery — April 2023- Fall 2023 Phase II: Educational & Creative Strategy — January 2024- Phase III: Education & Creative Implementation — 2024-2025 Phase IV: Campaign Monitoring & Continuous Improvement

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Allina Health CANCER INSTITUTE

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CALGB INTERSPORE ACRIN NCICB

CALGB 150012/150007 and ACRIN 6657

Investigation of
Serial studies to
Predict
Your
Therapeutic
Response with
Imaging and Molecular
Ana-
Lysis

I SPY WITH MY LITTLE EYE ... A BIO-MARKER BEGINING WITH X...

P.I. – Laura Esserman, M.D. UCSF

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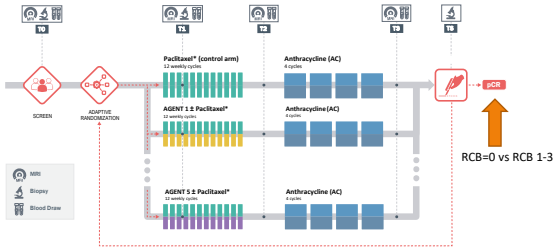
I-SPY 2 TRIAL Study Design – Pathologic Complete Response



HR+/HER2- patients with low-risk 70- gene (MammaPrint) Scores are not enrolled in I-SPY2 Agilent 44K IDE

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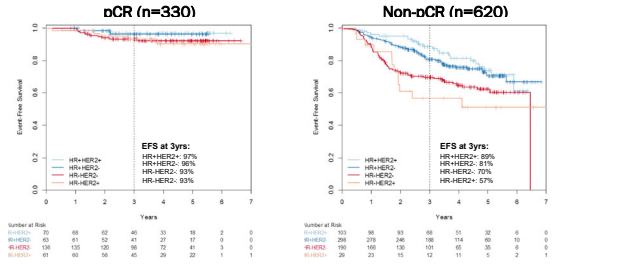
Event Free Survival by pCR & non-pCR



Yee, et al. JAMA Oncol 2020 PMID: 32701140

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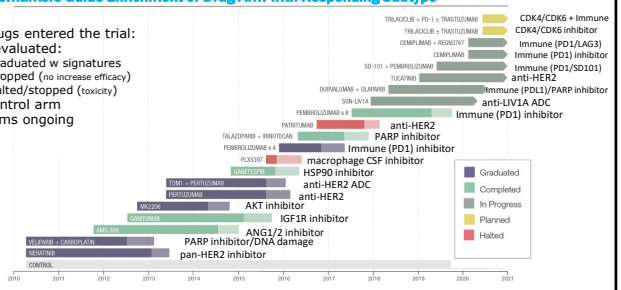
Timeline of Investigational Drugs and Graduating Subtypes

Biomarkers Guide Enrichment of Drug Arm with Responding Subtype

17 drugs entered the trial:
- 13 evaluated:
  - 6 graduated w signatures
  - 5 dropped (no increase efficacy)
  - 2 halted/stopped (toxicity)
- 1 control arm
- 5 arms ongoing



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IMPACT OF CLINICAL TRIALS

- Clinical trials offer the best care for patients with cancer
- Substantial barriers exist in making clinical trials more broadly applicable to cancer patients
- New clinical trial designs can identify active agents to bring them to standard-of-care more rapidly
- Many new strategies and drugs must be tested in clinical trials to "end cancer as we know it"
  - Risk reduction – tobacco control
  - Screening – mammography
  - Local (surgery, radiation) and systemic (drug) therapy
  - Cancer survivorship

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