Cancer Research Consortium of West Michigan
P: 616.391.1230 | 800.336.6299 | www.crcwm.org

FAST FACTS

A232402CD – PAGODA

Randomized Trial of a Proactive Graduated Dose Modification Algorithm for FOLFOX Chemotherapy to Prevent Unplanned Delays
(NCT07283939)

3.21 Documentation of Disease: Gastrointestinal Cancer

- **Histologic Documentation:** Histologic confirmation of invasive cancer that is confirmed or suspected to arise from the gastrointestinal (GI) tract.
- **Stage:** Any stage for which FOLFOX-based chemotherapy is a clinically-indicated, standard-of-care treatment (adjuvant, neoadjuvant, or first-line chemotherapy).
- **Tumor Site:** Eligible primary tumor sites include the esophagus, gastroesophageal junction, stomach, small intestine, ampulla of Vater, appendix, colon and rectum, as well as cancers of unknown primary with suspected GI origin.

3.2.2 Treatment Setting

- Prior systemic therapy for GI cancer (other than cycle 1 of FOLFOX-based chemotherapy) is not allowed. Prior radiation-sensitizing chemotherapy is permitted.
- The planned duration of FOLFOX-based chemotherapy must be at least four cycles (1 cycle = 14 days).
- Cycle 1, day 1 of FOLFOX-based chemotherapy must be completed 1 to 8 days prior to registration.
- Cycle 1, day 1 of FOLFOX-based chemotherapy must include minimum ordered doses of oxaliplatin (≥65 mg/m2) and infusional 5-FU (2400 mg/m2/46 hours). Use of the 5-FU bolus is at the discretion of the treating physician.
- Concomitant monoclonal antibodies are permitted during FOLFOX-based chemotherapy (e.g. anti-VEGF, anti-EGFRs, anti-PD1/PDL1, and anti-HER2).
- Patients receiving concomitant therapy with irinotecan or docetaxel are not eligible.
- Patients who require primary prophylactic white blood cell growth factor with cycle 1 of FOLFOX chemotherapy due to high risk for fever and neutropenia are not eligible.
- Patients with history of hypersensitivity reaction to oxaliplatin or other platinum-based drugs, to fluorouracil, or to leucovorin, and the excipients in their formulations are not eligible.

3.2.3 Age ≥ 18 years

3.2.4 ECOG Performance Status ≤ 2

3.2.5 Required Initial Lab Values:

Absolute Neutrophil Count (ANC)	≥ 1,000/mm3
Platelet Count	≥ 100,000/mm3
Total Bilirubin	≤ 3 x upper limit of normal (ULN)
AST (SGOT)/ALT (SGPT)	≤ 5 x upper limit of normal (ULN)
Calc. Creatinine Clearance	≥ 30 mL/min

3.2.6 Not pregnant and not nursing, because this study involves agents that have known genotoxic, mutagenic and teratogenic effects.

Therefore, for women of childbearing potential only, a negative pregnancy test done ≤ 30 days prior to registration is required.

3.2.7 Comorbid Conditions

- **Brain metastases:** Patients with treated brain metastases are eligible if follow-up brain imaging after CNS-directed therapy shows no evidence of progression.
- **HIV:** Patients with known HIV infection are eligible if receiving effective anti-retroviral therapy with undetectable viral load within 6 months prior to registration.
- **Hepatitis B:** Patients with known chronic hepatitis B virus (HBV) infection are eligible if HBV DNA is undetectable when measured within 6 months prior to registration.
- **Hepatitis C:** Patients with a known history of hepatitis C virus (HCV) infection are eligible if HCV RNA is undetectable when measured at least 12 weeks after completion of anti-viral therapy.
- **Cardiac function:** Patients with a known history or current symptoms of cardiac disease are eligible if the New York Heart Association Functional Classification is class I or II (heart failure with no more than slight limitation of physical activity).
- **Congenital long QT syndrome:** Patients with a known history of congenital long QT syndrome are ineligible.
- **Dihydropyrimidine dehydrogenase (DPD) deficiency:** Patients with known DPD deficiency are ineligible.

3.3 Non-Patient (Oncology Physician or Oncology Advanced Practice Provider) Eligibility

Medical oncologists and oncology advanced practice providers meeting the eligibility criteria for non-patients will be recruited to the study to complete a brief survey about their experience with the PAGODA dose modification algorithm. Participation of oncology physicians and oncology advanced practice providers is voluntary.

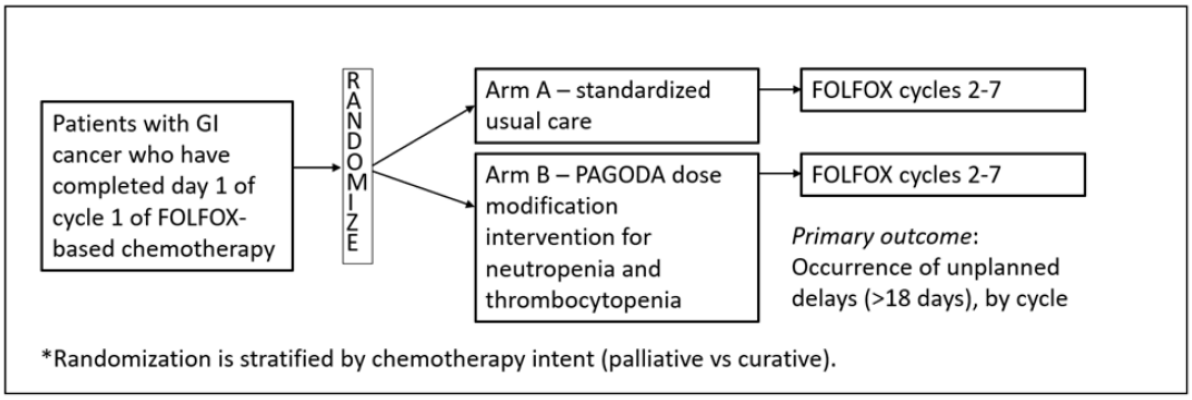
3.3.1 Relationship to patient participant: The non-patient provider participant is a medical oncologist or oncology advanced practice provider with responsibility for signing and making necessary modifications to chemotherapy orders for a subject assigned to the intervention arm (Arm B). Non-patient participants may not be enrolled more than once over the course of the study.

3.3.2 English language proficiency: The non-patient participant must be proficient in the English language.

3.3.3 Age: The non-patient participant must be age 21 years or older.

Schema

1 Cycle = 14 Days



Registration and randomization happen simultaneously. Active study participation is complete after the first of 1) completion of day 1 of last planned treatment cycle, as determined by the treating physician, or 2) completion of day 1 of cycle 7 of FOLFOX-based chemotherapy. The duration of treatment after completion of study participation is at the discretion of the treating physician. Patients will be followed for 2 years after registration, or until death, whichever comes first.