# NOSI: Research on Oral Anticancer Agents in the Contexts of Utilization, Adherence, and Health Care Delivery

NOT-CA-20-026

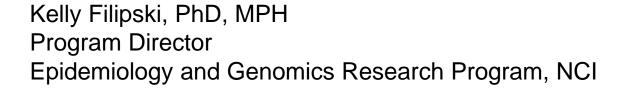
Available date: May 25, 2020

Expiration date: May 8, 2023



#### Webinar Presenters

Kate Castro, RN, MS, AOCN® Program Director Healthcare Delivery Research Program, NCI



Wendy Nelson, PhD, MPH
Program Director
Behavioral Research Program, NCI







# NCI DCCPS Organizational Structure

Division of Cancer Control and Population Sciences (DCCPS)

Healthcare Delivery Research Program Behavioral Research Program Epidemiology and Genomics Research Program Surveillance Research Program

The **Division of Cancer Control and Population Sciences (DCCPS)** aims to reduce cancer risk, incidence, and death, and enhance quality of life for cancer survivors.

#### cancercontrol.cancer.gov

# Agenda

- Background
- NOSI Details
- Resources
- Questions and Answers

Questions about specific aims or grant application details will not be addressed

# Background

## Background

- Molecularly targeted oral anticancer (OAC) medications have transformed cancer care
- OAC medications offer many potential advantages over traditional IV chemotherapy
  - Convenient home-based treatment
  - A sense of control over treatment
  - Avoid IV infusions, trips to hospital or clinic
- Potential downsides of OAC medications
  - Complex treatment regimens, often in addition to other medication regimens
  - OAC medications require strict adherence to be effective
  - Patients/caregivers are responsible for symptom management
  - Financial burden
  - Difficulties acquiring OAC medication



# **NOSI** Details

# Why do we need this Notice of Special Interest?

- Utilization
  - Little information is available on the adoption of newly approved targeted oral agents
  - Little information is available on off-label use of oral agents
  - Are targeted oral agents being prescribed appropriately?
- Adherence
  - Strict adherence is critical to achieving an optimal clinical outcome
  - Suboptimal adherence may lead to relapse, side-effects, unnecessary treatment changes, increased use of health care resources
- Health Care Delivery
  - Health care systems need to establish new roles, responsibilities, safety standards, patient education strategies for targeted oral therapies
  - Home-based treatment with targeted oral therapy requires new models of care coordination

# Research Objectives

 Characterize patient and provider factors influencing utilization of oral anticancer agents

 Identify the structural, systemic, and psychosocial barriers to adherence

 Develop models and strategies to improve safe and effective delivery of oral anticancer agents so that clinical outcomes are optimized

#### Considerations

- Applicants are encouraged to focus on at least one of the following
  - Specific type of cancer
  - Class of drugs
  - Patients subject to disparities
- Studies may be observational/descriptive or include interventions; observational studies should emphasize modifiable factors for future interventions
- Studies may focus on utilization, adherence, or health care delivery issues related to oral anticancer agents (no need to study everything)
- Consult your Program Director if you have questions

#### Research Priorities

- Cross-disciplinary collaborations (e.g., pharmacists, research nurses, social workers, financial navigators)
- Studies focused on newer molecularly targeted therapies
- Inclusion of medically underserved populations
- Primary data collection is encouraged

## **Utilization Challenges**

- Understand how targeted therapies are being prescribed and used
  - Disparities in access
  - Off-label use
- Potential research questions:
  - What are the patient and provider characteristics associated with prescribing and use of molecularly targeted agents?
  - Are there sociodemographic or health-related factors (e.g., comorbidities) that affect utilization?
  - -What are current trends in utilization of newly approved targeted oral therapies?

### Adherence Challenges

- Understand how cognitive, affective, and motivational processes influence adherence behavior
  - Beliefs about the safety and effectiveness of a "pill"
  - Depression, anxiety
- Potential research questions:
  - How do patients perceive the risks associated with oral therapy, and how do these risk perceptions influence adherence?
  - Are there major differences in patterns of adherence depending on the duration or complexity of the treatment regimen?
  - How do financial considerations (e.g., out-of-pocket costs) influence adherence?

# Health Care Delivery Challenges

- Understand how health care delivery systems are adapting to meet standards for safe administration and the educational needs of patients and caregivers
  - Symptom management
  - Coordination of care
- Potential research questions:
  - What system, health care team, provider, and patient-level factors are associated with the safe administration of oral agents?
  - How does reimbursement affect symptom management and monitoring?
  - What care delivery models lead to enhanced patient reporting of side effects and timely response from the clinical team?

# Resources

# Related Funding Opportunity Announcements

Submit applications for this initiative using one of the following funding opportunity announcements (FOAs) or any reissues of these announcements through the expiration date of this notice.

- PAR-18-869: Modular R01s in Cancer Control and Population Sciences (R01 Clinical Trial Optional)
- PAR-18-559: Cancer Prevention and Control Clinical Trials Grant Program (R01 Clinical Trial Required)
- PA-19-056 : NIH Research Project Grant (Parent R01 Clinical Trial Not Allowed)
- PAR-18-290: National Cancer Institute Program Project Applications (P01 Clinical Trial Optional)
- PA-18-722: Improving Patient Adherence to Treatment and Prevention Regimens to Promote Health
  - (R01 Clinical Trial Optional)
- PAR-18-021: NCI Small Grants Program for Cancer Research (R03 Clinical Trial Optional)
- PAR-19-309: Stimulating Innovations in Behavioral Intervention Research for Cancer Prevention and Control

(R21 Clinical Trial Optional)

All instructions in the SF424 (R&R) Application Guide and the funding opportunity announcement used for submission must be followed.

## **Program Contacts**

Wendy Nelson, PhD
<a href="mailto:Nelsonw@mail.nih.gov">Nelsonw@mail.nih.gov</a>
240-276-6971

Adherence

Kate Castro, RN, MS, AOCN®

Kathleen.Castro@nih.gov

240-276-6834

Health Care Delivery

Kelly Filipski, PhD Kelly.Filipski@nih.gov 240-276-6841 Utilization

# Questions

# U.S. Department of Health & Human Services National Institutes of Health / National Cancer Institute

cancercontrol.cancer.gov

1-800-4-CANCER