Pre-Application Webinar

RFA-CA-18-018

Prevention of HPV-related Cancers in HIV-infected individuals: United States-Latin American-Caribbean Clinical Trials Network: Partnership Centers (U54)

Vikrant Sahasrabuddhe, MBBS, MPH, DrPH
Division of Cancer Prevention
National Cancer Institute
sahasrabuddhevv@mail.nih.gov

NIH NATIONAL CANCER INSTITUTE

Oct 12, 2018

RFA-CA-18-018: Purpose

- Facilitate the design, conduct, and completion of clinical trials for improving prevention of human papillomavirus (HPV)-related cancers in human immunodeficiency virus (HIV)-infected individuals.

- Support a network of international collaborative sites conducting meritorious and appropriately designed prevention clinical trials in low- and middle-income countries (LMICs) in the Latin American and Caribbean (LAC) region via a U54 Partnership Centers mechanism.

HPV-mediated carcinogenesis in the context of HIV/AIDS

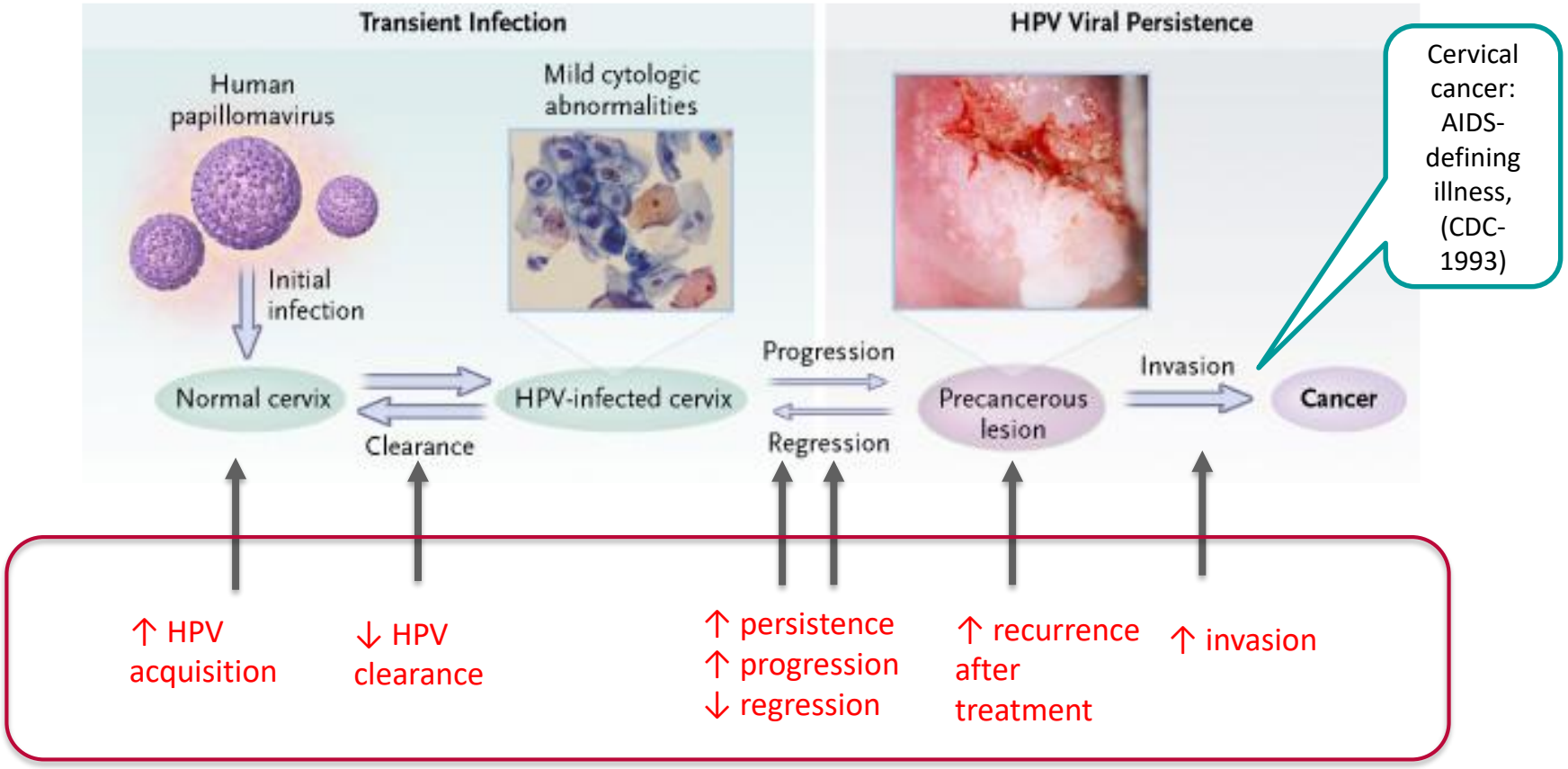


Figure ref: Wright & Schiffman, 2003 NEJM

RFA-CA-18-018

Background

- A wide spectrum of interventions (vaccines, screening, pre-cancer treatment) have been/are being discovered for the prevention of HPV-related cancers, yet evaluation and implementation in high-risk HIV+ individuals has been limited.
  - Inadequate evidence on best methods, algorithms, and follow-up protocols.
  - Unique immunosuppression-related clinical issues in context of HIV
- Clinical trials to resolve unanswered questions can inform clinical care recommendations and public health practice and ultimately contribute to reducing the burden of highly preventable HPV-related cancers in HIV-infected individuals.

RFA-CA-18-018

Rationale for focusing on the Latin American and Caribbean (LAC) region

- High HIV burden (2 million HIV+) and high cervical cancer burden
- Large public investments in HIV/AIDS care (models for HIV+ treatment for other LMICs)
- Recent strong commitments for HPV vaccination and HPV-based screening
- Strong US academic and clinical partnerships
- Long-standing NIH-funded HIV clinical trials infrastructure
  - Leading sites for landmark HIV trials (e.g., HPTN052 'Breakthrough of the Year 2011')
- Middle-income settings with highly educated and capable workforce
- Minimal time-zone differences facilitating effective coordination

Map: http://www.worldbookonline.com

RFA-CA-18-018: Key Requirements

- Each proposed U54 Partnership Center must be based on a collaboration between a research institution in the United States (as the applicant institution) and partnering institution(s) in LMICs in the LAC region.

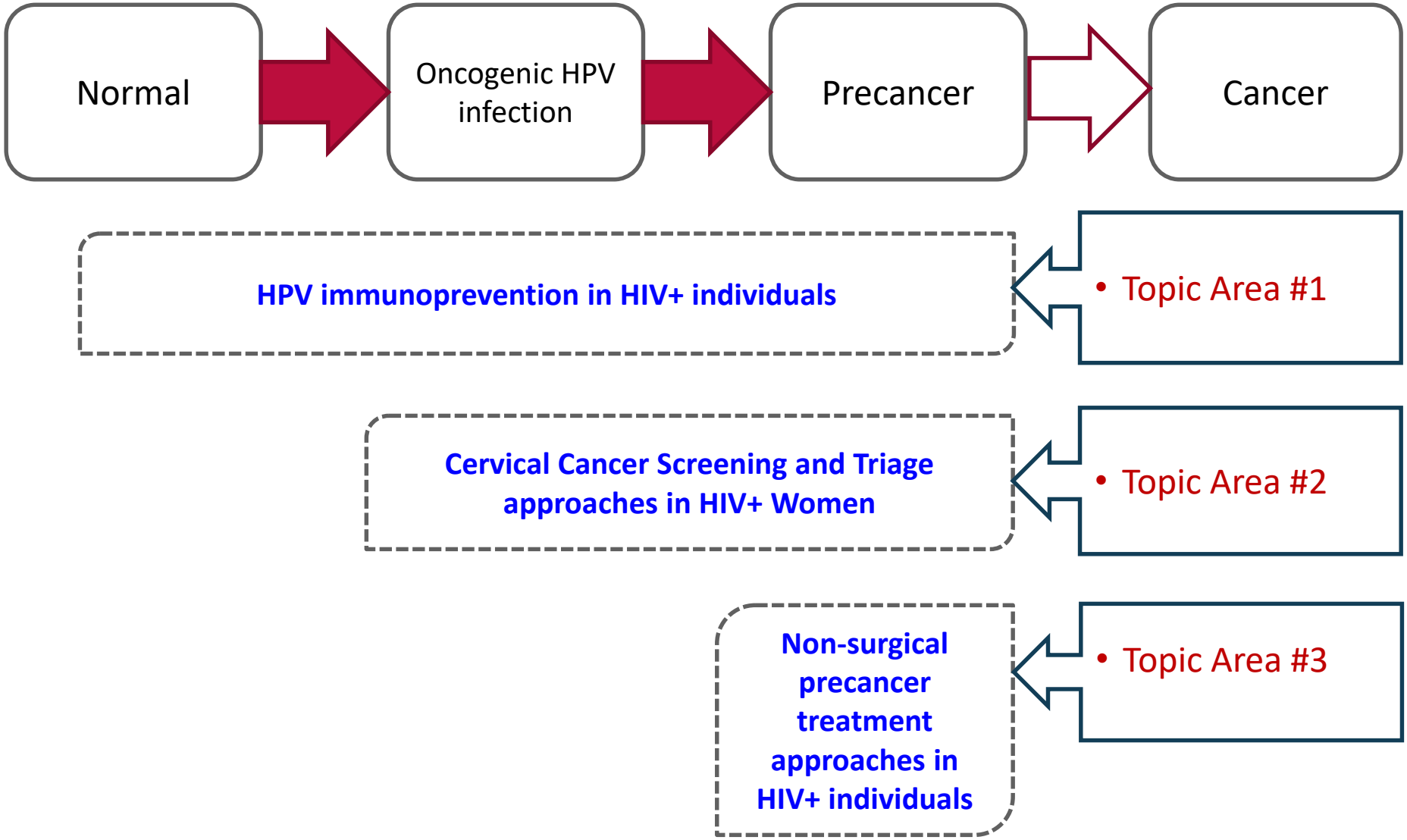
- The proposed clinical trials should be focused on optimizing clinical prevention interventions among HIV-infected individuals, including immunoprevention (vaccination), screening and triage, and precancer treatment.

RFA-CA-18-018: Requirements

- Each Partnership Center application must propose a ***Clinical Trials Program*** that will propose, develop, conduct, and complete three prevention clinical trials within the 5-year project period.

- As infrastructure supporting the Clinical Trials Program, each Partnership Center should include the following Cores:
  - **Administrative and Coordinating Core**
  - **Data Management and Statistical Core**
  - **Central Laboratory Core**

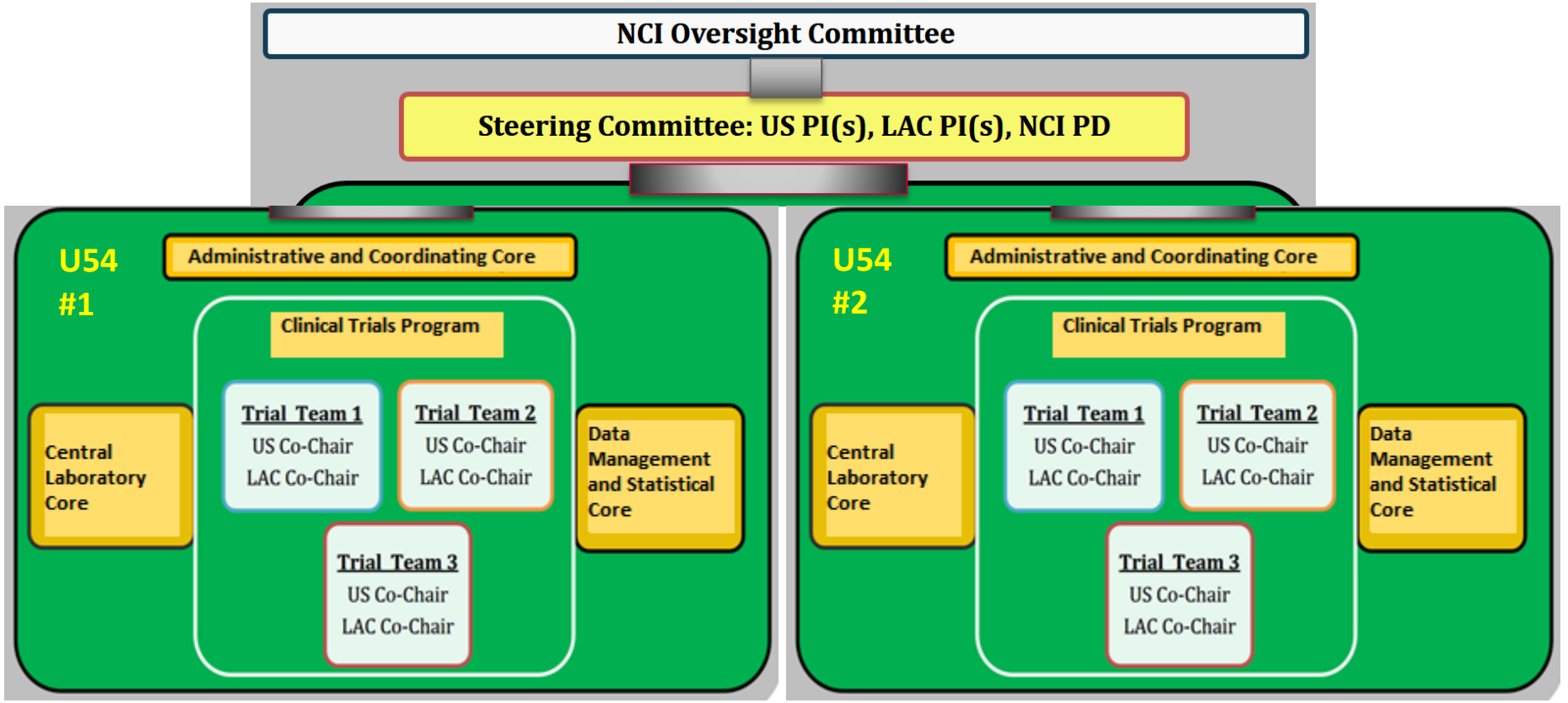
RFA-CA-18-018
Clinical Trials Program on Prevention of HPV-related Cancer in HIV+ Individuals: Central Research Thematic Areas



RFA-CA-18-018

Prevention of HPV-related Cancers in HIV-infected individuals: United States-Latin American-Caribbean Clinical Trials Network

Two U54 Specialized Center Cooperative Agreement 'Partnership Center' awards to be funded in FY2019



One clinical trial protocol must be a fully developed study, with adequate conceptual and implementation details for launch within the first year of the study period (presented as a 'Delayed Start Study').
Concepts for the other two clinical trial protocols may have limited details about trial implementation known at the time of application, and could be proposed as developmental concepts, with an expectation that they may be launched in later years but completed within the 5-year project period (presented as 'Delayed Onset Study').

RFA-CA-18-018
Questions from Prospective Applicants

Webinar slides/recording and FAQs will be archived on https://prevention.cancer.gov/ulacnet

For additional questions, please contact sahasrabuddhevv@mail.nih.gov

NATIONAL CANCER INSTITUTE

www.cancer.gov **www.cancer.gov/espanol**