# Consortium on Translational Research in Early Detection of Liver Cancer: Pre-Application Webinar for RFA-CA-22-031 and RFA-CA-22-032

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# Disclaimer and Points to Note

- Today's presentation provides a high-level overview of TLC and is not a substitute for the FOAs. Please read the relevant FOA for details.
- After today's orientation Webinar, any future questions must be directed via email to the contacts listed on each FOA. Phone calls are discouraged.
- All the slides will be posted on the TLC Website (https://prevention.cancer.gov/major-programs/translational-liver-cancer-consortium).
- Recordings of today's proceedings will be made available.

# Challenges

- Current biomarkers for HCC surveillance lack sensitivity/specificity. Need validation/verification studies combining biomarkers, clinical parameters, and/or imaging modalities to improve HCC surveillance and increase early detection of HCC.
- Access to cohorts of patients with cirrhosis attributable to viral (HBV, HCV) and non-viral (NAFLD/NASH, ALD) etiology.
- High prevalence of cirrhosis- the stratification of patients to high-risk groups for progression to HCC will have clinical benefits.
- Burden of HCC is higher in minority populations and the performance of biomarkers in these populations needs to be addressed.

# Translational Liver Cancer Program Objectives

- Advancing translational research in the early detection of liver cancer,
- Studies to improve the surveillance of liver cancer in members of high-risk populations,
- Increase the fraction of liver cancer detected at an early stage, and
- Better stratify patients at risk of developing liver cancer.
- A major collaborative effort of the Translational Research Centers (TRCs) will be establishing an integrated blood and image repository with annotated clinical data.

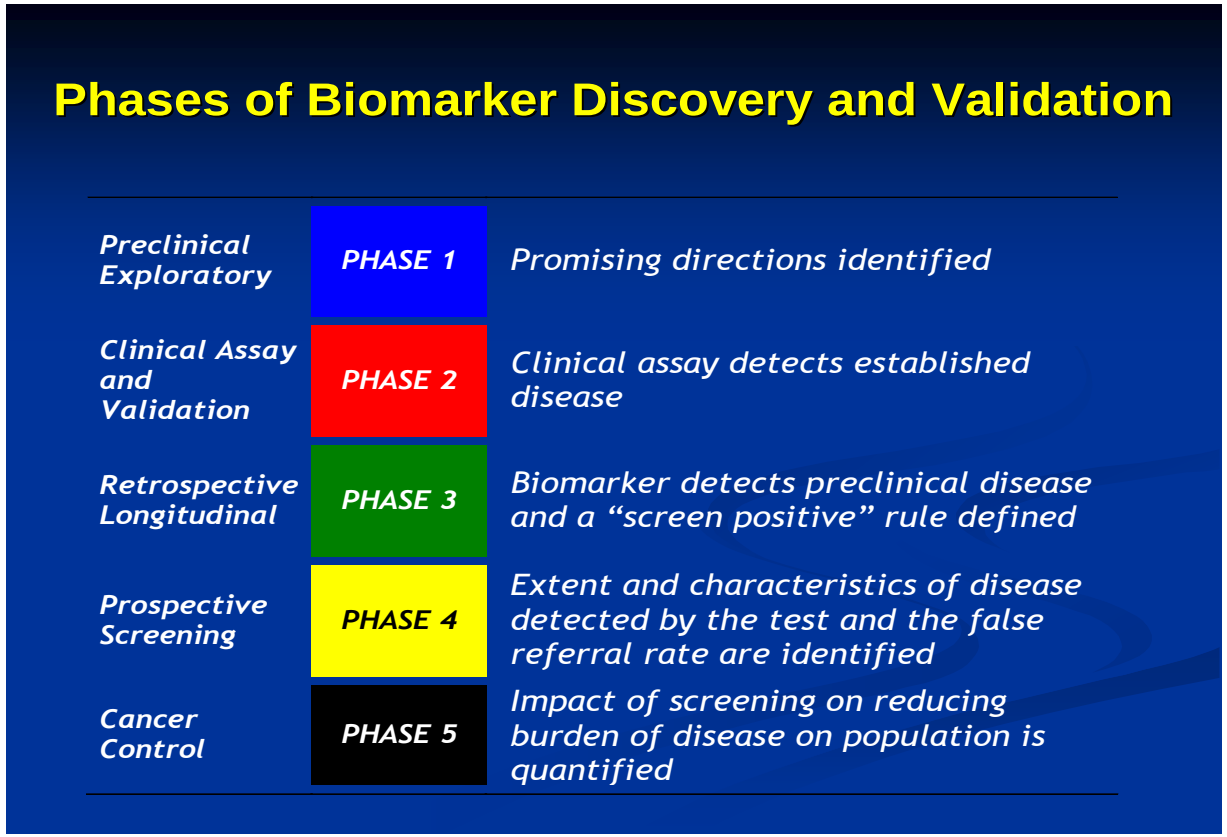
# Future Consortium Collaborative Projects

Major unmet need is the ability to differentiate whether an indeterminate nodule identified during HCC screening is benign or malignant. Indeterminate nodules (LR3/LR4 lesions) are found in ~20% patients undergoing HCC screening. Current guidelines recommend these nodules to be evaluated by surveillance (CT or MRI) or biopsy until HCC diagnosis.

***Project Goals***

A combination of clinical, blood-based biomarkers, and image-based biomarkers are being used to determine the risk of HCC among patients with cirrhosis and indeterminate nodules found during HCC screening

# Guidelines for Biomarker Development




Phases of Biomarker Development for Early Detection of Cancer
Margaret Sullivan Pepe et al., J Natl Cancer Inst. 2001 Jul 18; 93(14): 1054–1061.

**PRoBE Study Design:**
**P**rospective-
Specimen-
Collection,
**R**etr**o**spective-
**B**linded-
**E**valuation

**Pivotal Evaluation of the Accuracy of a Biomarker Used for Classification or Prediction: Standards for Study Design**
Margaret Sullivan Pepe et al.,
J Natl Cancer Inst. 2008 Oct 15;
100(20): 1432-1438.

# PD/PI: Primary Responsibilities

- Defining objectives and approaches, conducting of experiments, and publishing reports of studies conducted under this award;
- Assuming responsibility and accountability to the applicant organization and to the NCI;
- Serving as voting members of the Consortium Steering Committee and attending Steering Committee meetings once a year;
- Accepting and implementing the goals, priorities, procedures, and policies agreed upon by the Steering Committee;
- Participation in collaborative Consortium research activities; and
- Implementing the approved research resource sharing plan.

# PD/PI: Collaborative Responsibilities

- Develop collaborations with other Translational Liver Cancer Sites (set-aside projects)
- Participate in Collaborative Group(s) meetings and team projects
- Participate in monthly and yearly Steering Committee Meetings
- Collaborate with DMCC on common research designs and protocol development (CDEs)
- Data sharing

# Application Checklist

- Is the application organized per instructions in the RFA?
- Have the special requirements been followed in developing the proposal (e.g., page limits, team structure, study designs, etc.)?
- Are the proposed specific aims achievable in the given timeframe?
- Have collaborations been established and are partners on board?
- Has a contact PI been identified for multi-PI proposals and communication and management plans developed?

# Thank you.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