

remove personal or business information including confidential, contact, or other identifying information. Comments should not include any information such as confidential information that would not be appropriate for public disclosure.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551-0001, not later than September 27, 2024.

A. Federal Reserve Bank of Minneapolis (Mark Rauzi, Vice President), 90 Hennepin Avenue, Minneapolis, Minnesota 55480-0291. Comments can also be sent electronically to MA@mpls.frb.org:

1. **NATCOM Bancshares, Inc.**, Superior, Wisconsin; to merge with Great River Holding Company, and thereby indirectly acquire RiverWood Bank, both of Baxter, Minnesota.

B. Federal Reserve Bank of Dallas (Karen Smith, Director, Mergers & Acquisitions) 2200 North Pearl Street, Dallas, Texas 75201-2272. Comments can also be sent electronically to Comments.applications@dal.frb.org:

1. **Karnes County National Bancshares, Inc.**, Karnes City, Texas; to become a bank holding company by acquiring The Karnes County National Bank of Karnes City, Karnes City, Texas.

Board of Governors of the Federal Reserve System.

Erin Cayce,

Assistant Secretary of the Board.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Medical Therapies for Locally Advanced Gastric Adenocarcinoma

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS. **ACTION:** Request for Supplemental Evidence and Data Submission **SUMMARY:** The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review on *Medical Therapies for Locally Advanced Gastric Adenocarcinoma*, which is currently being conducted by the AHRQ's Evidence-based Practice

Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

DATES: *Submission Deadline* on or before September 27, 2024.

ADDRESSES:

Email submissions: epc@ahrq.hhs.gov.

Print submissions:

Mailing Address: Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E53A, Rockville, MD 20857

Shipping Address (FedEx, UPS, etc.): Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E77D, Rockville, MD 20857

FOR FURTHER INFORMATION CONTACT:

Kelly Carper, Telephone: 301-427-1656 or Email: epc@ahrq.hhs.gov.

SUPPLEMENTARY INFORMATION: The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for *Medical Therapies for Locally Advanced Gastric Adenocarcinoma*. AHRQ is conducting this review pursuant to Section 902 of the Public Health Service Act, 42 U.S.C. 299a.

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (e.g., details of studies conducted). We are looking for studies that report on *Medical Therapies for Locally Advanced Gastric Adenocarcinoma*. The entire research protocol is available online at: <https://effectivehealthcare.ahrq.gov/products/gastric-cancers/protocol>.

This is to notify the public that the EPC Program would find the following information on *Medical Therapies for Locally Advanced Gastric Adenocarcinoma* helpful:

- A list of completed studies that your organization has sponsored for this topic. In the list, please *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number.*

- *For completed studies that do not have results on ClinicalTrials.gov*, a summary, including the following elements, if relevant: study number, study period, design, methodology,

indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/enrolled/lost to follow-up/withdrawn/analyzed, effectiveness/efficacy, and safety results.

- *A list of ongoing studies that your organization has sponsored for this topic.* In the list, please provide the *ClinicalTrials.gov* trial number or, if the trial is not registered, the protocol for the study including, if relevant, a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.

- Description of whether the above studies constitute *ALL Phase II and above clinical trials* sponsored by your organization for this topic and an index outlining the relevant information in each submitted file.

Your contribution is very beneficial to the Program. Materials submitted must be publicly available or able to be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on topics not included in the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the email list at: <https://effectivehealthcare.ahrq.gov/email-updates>.

The review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.

Key Questions (KQ)

KQ1: What is the comparative effectiveness and comparative harms of medical therapies for management of non-metastatic, locally advanced gastric adenocarcinoma?

KQ2: Do treatment effectiveness and harms vary by cancer stage, histology (e.g. intestinal, diffuse, signet ring cell), biomarkers (e.g. microsatellite instability-high [MSI-H] or mismatch repair-deficient [MMR-deficient], claudin, human epidermal growth factor receptor 2 [HER-2], programmed death-ligand 1 [PDL1], Epstein-Barr virus [EBV]), or genetic predisposition (e.g. cadherin-1 [CDH1])?

KQ3: Do treatment effectiveness and harms vary by age, functional status (e.g. Karnofsky score, Eastern Cooperative Oncology Group [ECOG] Performance Status score), medical comorbidities or conditions that increase risk of toxicity with specific therapy (e.g. existing neuropathy, prior radiation therapy, history of autoimmune disease)?

PICOTS (POPULATION, INTERVENTIONS, COMPARATORS, OUTCOMES, TIMING, AND SETTING)

PICOTS	Inclusion	Exclusion
Population	All KQs: Adults (18 years or older) with primary, non-recurrent, non-metastatic locally advanced gastric adenocarcinoma stage T2N0 or higher. KQ1: Subgroups of interest may include patients who previously received endoscopic therapy or surgery, patients who are non-surgical candidates, and patients with initially unresectable disease. KQ2: Subgroups of interest may include patients with gastroesophageal junction (GEJ) cancer.	Recurrent cancer, metastatic cancer, early stage (T1aN0 and T1bN0), stage 4 cancer, GEJ cancer patients treated in a predominantly esophageal cancer cohort with an esophageal treatment paradigm, gastrointestinal stromal tumors (GIST), neuroendocrine tumors, gastric lymphoma, MALToma, other rare gastric cancers.
Interventions	All KQs. Cancer-directed medical therapies administered either alone or in any combination, and may be neoadjuvant, adjuvant, or perioperative (neoadjuvant and adjuvant) and in any sequence: <ul style="list-style-type: none"> • Chemotherapy including but not limited to: Fluoropyrimidine-based therapy: FOLFOX, XELOX, FLOT, SOX, ECF. • Radiation including but not limited to external beam radiation, intra-operative electron radiation. • Chemoradiation • HIPEC • Immunotherapy (e.g., ipilimumab, nivolumab) • Targeted therapy (e.g., anti-HER2 monoclonal antibodies). 	<ul style="list-style-type: none"> • Surgical management exclusively. • Intervention is not well specified (e.g., study reports intervention as “adjuvant chemotherapy” without describing the regimen). • Palliative interventions.
Comparators	All KQs <ul style="list-style-type: none"> • Any comparator • No comparator (for biomarker-targeted interventions) 	N/A.
Outcomes	All KQs <ul style="list-style-type: none"> • Overall survival • Progression-free survival • Nutritional assessment • Quality of life, using validated scales • Direct moderate-severe treatment adverse events (grade 3, 4, 5). • Direct mild treatment adverse events (grade 1, 2) • Indirect adverse events from treatment (e.g., long-term opioid use for pain management). 	N/A.
Timing	All KQs: Any follow-up duration for grade 3–5 or indirect adverse events and quality of life; minimum of 1 year for grade 1–2 adverse events; minimum of 3 months for remaining outcomes.	N/A.
Setting	All KQs: <ul style="list-style-type: none"> • Countries rated as very high on the 2024 Human Development Index (if study is multinational, at least one study center is in a country rated very high). 	N/A.
Study Design and Other Criteria.	All KQs: <ul style="list-style-type: none"> • Randomized controlled trials • Non-randomized studies of interventions (experimental or observational) with a concurrent comparator and well-controlled for confounding (at minimum account for age, stage, functional status, and comorbidities). • Single-arm studies (for biomarker-targeted interventions) • Published in English-language • Published in 2006 or later 	Case reports, case series, commentaries, cross-sectional studies, reviews, qualitative studies.

Abbreviations: ECF = epirubicin, cisplatin, fluorouracil; FLOT = fluorouracil, leucovorin, oxaliplatin and docetaxel; FOLFOX = leucovorin, fluorouracil, and oxaliplatin; HER2 = human epidermal growth factor receptor 2; HIPEC = hyperthermic intraperitoneal chemotherapy; KQ = key question; SOX = tegafur, gimeracil, oteracil, and oxaliplatin; XELOX = capecitabine and oxaliplatin.

Marquita Cullom,
Associate Director.

[FR Doc. 2024-19344 Filed 8-27-24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Award of a Single Source Cooperative Agreement To Fund California Department of Public Health; Chicago Department of Public Health; Delaware Department of Health and Social Services; Florida Department of Health; Georgia Department of Public Health; Houston Department of Health and Human Services; Illinois Department of Public Health; Indiana State Department of Health; Los Angeles County Department of Public Health; Michigan Department of Health and Human Services; Mississippi State Department of Health; New Jersey Department of Health and Senior Services; New York City Department of Health and Mental Hygiene; New York State Department of Health; North Carolina Department of Health and Human Services; Oregon Health Authority; Pennsylvania Department of Health; Philadelphia Department of Public Health; Puerto Rico Department of Health; San Francisco Department of Public Health; Texas Department of State Health Services; Virginia Department of Health; and Washington State Department of Health

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS), announces 23 separate awards to fund the California Department of Public Health; Chicago Department of Public Health; Delaware Department of Health and Social Services; Florida Department of Health; Georgia Department of Public Health; Houston Department of Health and

Human Services; Illinois Department of Public Health; Indiana State Department of Health; Los Angeles County Department of Public Health; Michigan Department of Health and Human Services; Mississippi State Department of Health; New Jersey Department of Health and Senior Services; New York City Department of Health and Mental Hygiene; New York State Department of Health; North Carolina Department of Health and Human Services; Oregon Health Authority; Pennsylvania Department of Health; Philadelphia Department of Public Health; Puerto Rico Department of Health; San Francisco Department of Public Health; Texas Department of State Health Services; Virginia Department of Health; and Washington State Department of Health.

The total amount of awards is approximately \$16,305,555 in Federal Fiscal Year (FFY) 2025, with an expected total funding of approximately \$81,527,775 for the five-year period of performance, subject to availability of funds. The awards will support implementation of the Medical Monitoring Project (MMP), an ongoing public health surveillance program funded since 2005 and designed to learn more about the experiences and needs of adults aged 18 or older living with HIV (PWH) in the United States.

DATES: The period for these awards will be June 1, 2025, through May 31, 2030.

FOR FURTHER INFORMATION CONTACT: Jason Crow, National Center for HIV, Viral Hepatitis, STD and TB Prevention, Centers for Disease Control and Prevention, 1600 Clifton Road, MS H24-5, Atlanta, GA 30333, Telephone: (404) 639-6395, E-Mail: jcrow@cdc.gov.

SUPPLEMENTARY INFORMATION: The single source award will support the collection of comprehensive clinical and behavioral information from persons carefully sampled to represent everyone diagnosed with HIV in the U.S. The data are collected through in-person or telephone interviews with participants and a two-year medical chart abstraction for all persons who have been in care. MMP produces nationally representative data on important sociodemographic, behavioral, and clinical characteristics among PWH in the U.S. MMP reports essential data on barriers to care and viral suppression, including social determinants of health and indicators of quality of life among PWH that are used to plan and monitor state and local HIV programs, inform national HIV clinical guidelines and assess national progress towards meeting the goals of the National HIV/AIDS Strategy for the United States

2022-2025, the Ending the HIV Epidemic in the United States (EHE) initiative, the HIV Care Continuum, and CDC's High-Impact Prevention (HIP) approach.

The 23 previously listed state, local and territorial health departments are in a unique position to conduct this work as (1) they are the only entities with legal authority to mandate the collection of public health surveillance data in their jurisdictions, (2) they can continue monitoring and reporting MMP data without lapse and (3) their selection can ensure adherence to the project's established scientific sampling strategy that ensures the national representativeness of MMP data.

Summary of the Award

Recipient: California Department of Public Health; Chicago Department of Public Health; Delaware Department of Health and Social Services; Florida Department of Health; Georgia Department of Public Health; Houston Department of Health and Human Services; Illinois Department of Public Health; Indiana State Department of Health; Los Angeles County Department of Public Health; Michigan Department of Health and Human Services; Mississippi State Department of Health; New Jersey Department of Health and Senior Services; New York City Department of Health and Mental Hygiene; New York State Department of Health; North Carolina Department of Health and Human Services; Oregon Health Authority; Pennsylvania Department of Health; Philadelphia Department of Public Health; Puerto Rico Department of Health; San Francisco Department of Public Health; Texas Department of State Health Services; Virginia Department of Health; and Washington State Department of Health.

Purpose of the Award: The purpose of these awards is to support implementation of NOFO PS25-0008 Medical Monitoring Project (MMP), an ongoing public health surveillance program funded since 2005 and designed to learn more about the experiences and needs of adults aged 18 or older living with HIV (PWH) in the United States.

Amount of Award: The total amount of awards is approximately \$16,305,556 in Federal Fiscal Year (FFY) 2025, with an expected total funding of approximately \$81,527,780 for the five-year period of performance, subject to availability of funds. The below table lists proposed FFY 2025 award amounts per recipient, subject to availability of funds.