

November 2, 2022

NHLBI Scientific Priority Areas for Research and Funding

Dr. Mike Pieck, NHLBI Catalyze Program Scientific Director

Dr. Denny Buxton, Division of Cardiovascular Sciences (DCVS)

Dr. Patricia Noel, Division of Lung Diseases and the National Center for Sleep Disorders Research (DLD, NCSDR)

Dr. Asif Rizwan, Division of Blood Diseases and Resources (DBDR)

Dr. George Mensah, Center for Translational Research and Implementation Science (CTRIS)

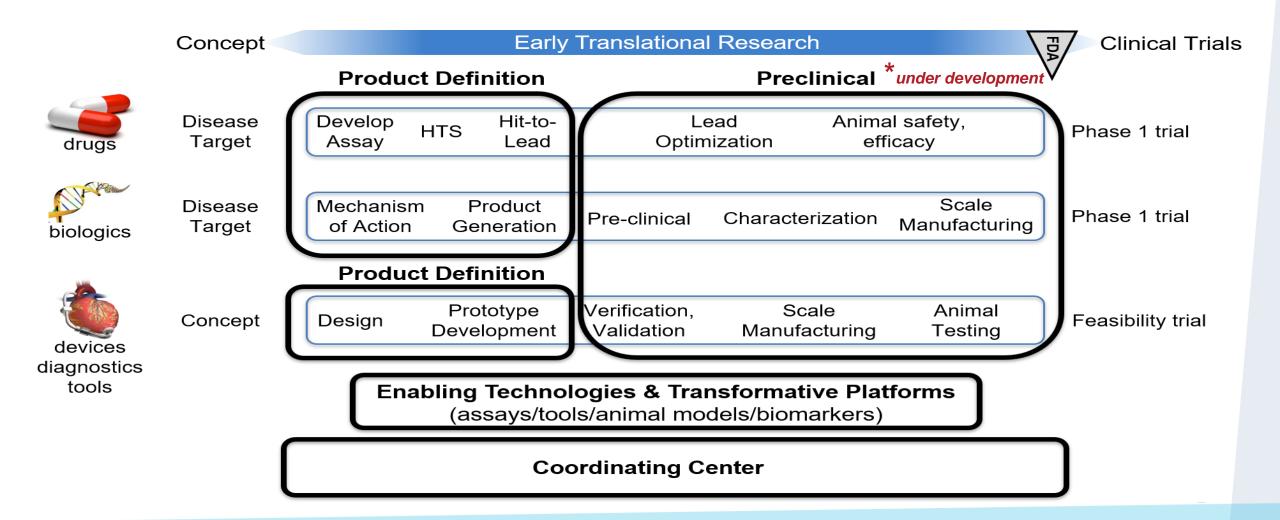
Website: www.nhlbicatalyze.org

Email: NHLBI_catalyze@mail.nih.gov, catalyze_info@rti.org



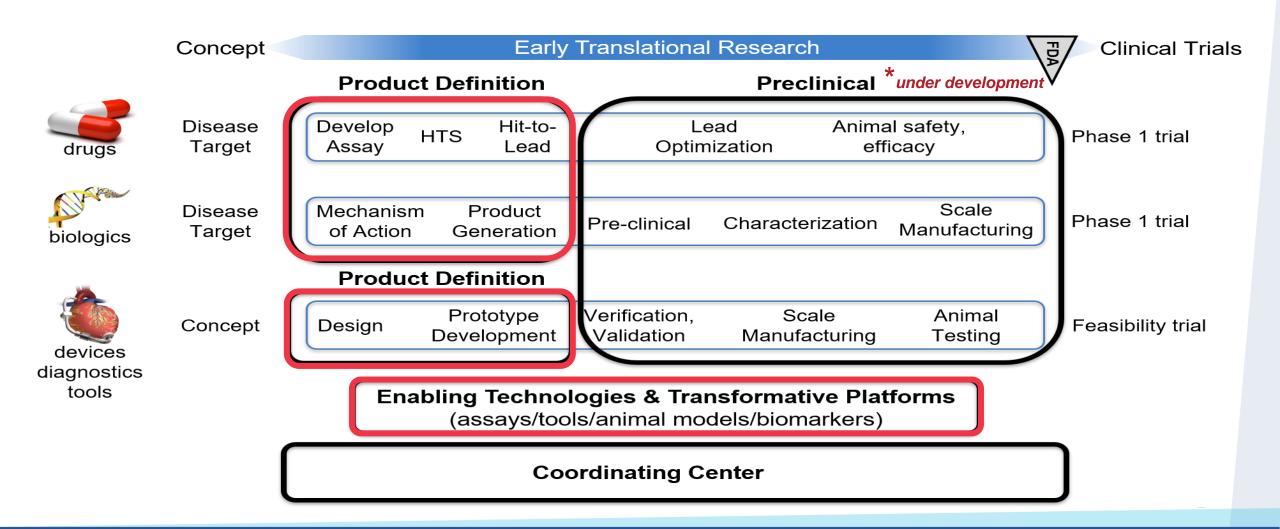


Program Components





Program Components





Product Definition Funding Opportunities

Application Deadline November 21, 2022

Enabling Technologies

 Enabling Technologies and Transformative Platforms for HLBS Research (<u>RFA-HL-23-010</u>)

Small Molecules and Biologics

- Target Identification and Validation, Preliminary Product/Lead Series Identification (<u>RFA-HL-23-011</u>)
- Preliminary Product/Lead Series
 Identification (RFA-HL-23-012)

Devices and Diagnostics

- Protype Design and Testing, Diagnostic Disease Target Identification, Assay Development and Research Tool Dev. (RFA-HL-23-013)
- Prototype Testing and Design
 Modification, Diagnostic Disease Target
 Assay Development, and Design
 Characterization, and Research Tool
 Testing and Validation (RFA-HL-23-014)



US-based academic, non-profit institutions, and US-owned for-profit institutions are eligible to apply



Product Definition Webinar

June 16th, 2022 12:00pm - 1:00pm Eastern

Title: Applying to the Catalyze Program: Tips from the director and programmatic offerings that set us apart

Dr. Mike Pieck, Emily Vernon, MMB, and Brailey Faris, MS

Duration: 1 hour

Presenters:

☐ View recording

The Catalyze Program is a translational science program that offers a unique set of resources to support you along your innovation journey in moving your projects into practical application. Accepted investigators not only receive clinical, manufacturing, and regulatory expertise from the Catalyze team, but have access to broader resources at RTI International, including market and value proposition assessments from the RTI Innovation Advisors. Interested in learning more?

Join Dr. Mike Pieck (the Catalyze Scientific Director) and members of RTI Innovation Advisors team ahead of the next application receipt deadline (due: July 21st, 2022) to:

- · learn what types of resources you have access to as a member of the Catalyze Program
- receive guidance for developing a competitive Catalyze application

https://nhlbicatalyze.org/events/recording-20220616



Product Definition Special Requirements Checklists

Special Requirements Checklist

- Enabling Technologies and Transformative Platforms (R33)
- RFA-HL-23-010

!!Update!!

- NOT-HL-22-015 *
- Do not include separate attachment for Milestones timelines and Project Management

Special Requirements Checklist

- Product Definition phased applications (R61/R33)
- RFA-HL-23-011
- RFA-HL-23-013

Special Requirements Checklist

- Product Definition (R33)
- RFA-HL-23-012
- RFA-HL-23-014

NHLBI Priority Areas

- Dr. Denny Buxton, Division of Cardiovascular Sciences (DCVS),
- Dr. Patricia Noel, Division of Lung Diseases and the National Center for Sleep Disorders Research (DLD, NCSDR),
- Dr. Asif Rizwan, Division of Blood Diseases and Resources (DBDR), and
- Dr. George Mensah, Center for Translational Research and Implementation Science (CTRIS).





Division of Cardiovascular Sciences

Denny Buxton 11/02/2022



Division of Cardiovascular Sciences - DCVS

- DCVS covers a wide range of science, from basic science and early translation through clinical trials to population sciences
- The Division is broken down into 7 branches:
 - Advanced Technologies and Surgery
 - Vascular Biology and Hypertension
 - Atherothrombosis and Coronary Artery Disease
 - Heart Development and Structural Diseases
 - Heart Failure and Arrhythmias
 - Epidemiology
 - Clinical Applications



DCVS Priority Areas

- ► Development of heart valves suitable for use in low-resource environments
- Diagnostics and therapeutics for rheumatic heart disease
- Improved methods for production of therapeutic extracellular vesicles optimized for efficacy and reproducibility
- Tailored biomaterials and biomimetic coatings for devices, designed to match the cellular milieu at the planned implantation site
- Improved methods for measurement of ambulatory blood pressure
- Development of novel diagnostics and therapeutic modalities for lymphatic disorders



DCVS Priority Areas

- ► Improved methods of monitoring blood flow in peripheral arterial disease
- Methods for the enhanced visualization of small blood vessels in vivo for preclinical and clinical brain imaging
- Novel approaches to the treatment of hypertension:
 - Cross-correlation of biomarker data and EHRs
 - Early identification and better monitoring using ML/AI technology
- New technologies for measuring arterial stiffness, including wearable devices that measure multiple cardiovascular outputs
- Novel diagnostics and therapeutics for preeclampsia
- Improved diagnostics and treatments for aortic aneurysms



DCVS Priority Areas

- Generate effective vaccines that target human proprotein convertase subtilisin kexin type 9 (PCSK9) and reduce LDL-C, perform proof of-principle studies in animal models
- Develop vaccines targeting other molecules involved in lipid metabolism like ApoC3 and ANGPTL3 & 4, and assess their effects on triglyceride levels
- Using Artificial Intelligence to improve diagnosis of ischemia-producing obstructive coronary stenoses on CT angiography
- Develop reliable Lipoprotein(a) assays that are isoform-independent using a monoclonal antibody that is specific to apo(a)



Division of Lung Diseases: Discovery to Application

National Heart, Lung, and Blood Institute (NHLBI) Discovery to Application

Patricia Noel, Ph.D.

Division of Lung Diseases, NHLBI
November 2, 2022





Division of Lung Diseases (DLD)





James Kiley, PhD, DLD Director



Matt Craig, PhD Lung Biology and Disease Branch (LBDB) Branch Chief

- Acute and Critical Care
- Lung Transplant
- Granulomatous, rare, Interstitial Lung Diseases
- Pulmonary Response to Infection, Microbiome, HIV/AIDS
- Developmental and Regenerative Biology
- Neonatal and Pediatric Development and Disease
- Integrative Lung Biology
- Lung Vascular Biology



Thomas Croxton, MD, PhD Airways Biology and Disease Branch (ABDB) Branch Chief

- Asthma
- Cystic Fibrosis
- COPD and Environment
- · Women's Health
- Genetics, -Omics, Advanced Technologies
- Digital Health and Informatics Technologies
- Integrative Lung Biology

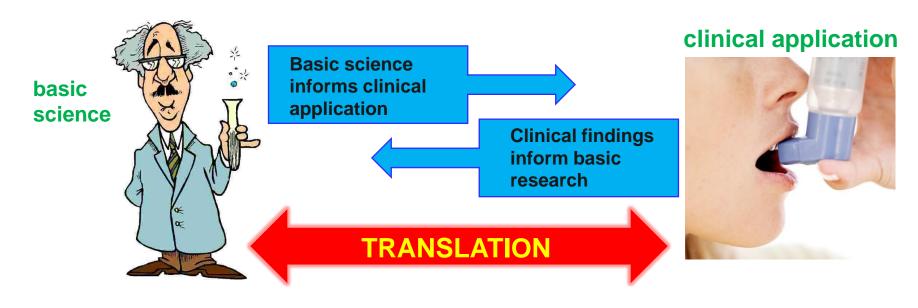


Marishka Brown, PhD National Center on Sleep Disorders Research (NCSDR), Director

- Sleep Disorders Medicine
- Prevention and Sleep Health
- Neurobiology and Sleep
- Chronobiology





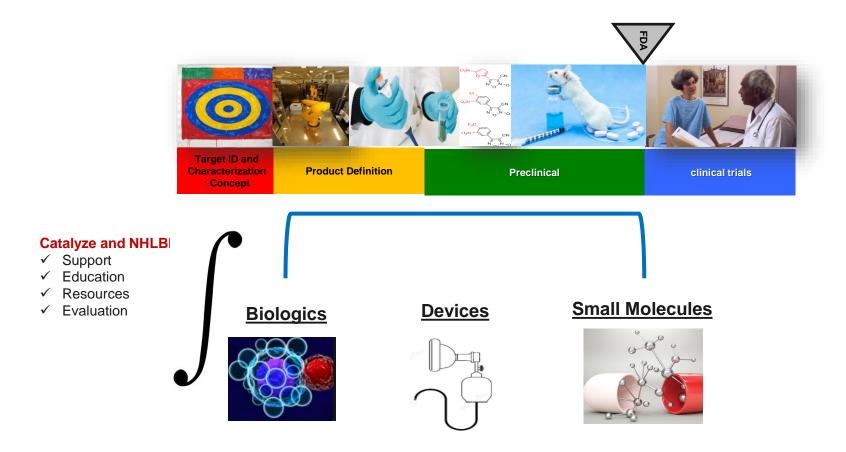


Asthma Inflammation Research (Serpil Erzurum, Cleveland Clinic)

- role of chronic inflammation and repeated, failed repair and resolution cycles in asthma
- development of novel diagnostics, treatments and monitoring tools based on pathobiology

- Successful translational research requires flexible support across the research continuum
- Multiple types of support and training efforts are needed beyond traditional mechanistic and clinical research methodology (e.g. intellectual property, commercialization, regulatory)
- Integration of diverse expertise and data, and standardization and sharing of data and biospecimens are necessary to enable prevention and disease-modifying interventions for targeted patient populations
- Continued evaluation and refinement will enhance efficiency and success of complex translational programs

Catalyze: Facilitating Development of Novel Interventions

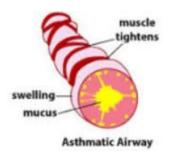




Active DLD Catalyze Project Examples

Mitigation of bronchoconstrictive effects of airway smooth muscle in asthma

 Small molecule inhibitor to abrogate tethering of ASM to surrounding matrix, reducing bronchoconstriction



Respiratory stimulant for use in critical care settings

 Novel class of small molecules for respiratory stimulation without blunting effects of analgesia



Bedside Diagnostic Imaging

• Mobile digital tomosynthesis (DGT) for high resolution imaging the ICU bedside





DLD Areas of Interest for Immediate Novel Products and Technologies

Disease modifying novel technologies/products for prevention and treatment of acute and chronic lung diseases

- Novel mucolytic drugs
- Formulations to overcome mucus barriers
- Formulations to deliver uniform dosing to distal airways
- Modulation of innate and adaptive pulmonary defenses against infection
- Novel therapeutics (companion diagnostics, if appropriate) for disease specific inflammatory, repair, and remodeling processes
- Novel therapeutics targeting extra-pulmonary processes that may contribute to development or worsening
 of lung and sleep disorders (e.g. metabolic abnormalities)

Digital Health and Informatics Technologies

- Apps, Tools, Sensors and biomonitoring technologies for climate change-related exposures and the impact on lung and sleep disorders
- Detecting, predicting, and/or monitoring lung and sleep-related disorders during pregnancy and/or the post-partum period
- Develop safe, accurate, and effective devices for use in neonatal, perinatal, and pediatric care settings
- Assessing the validity and reliability of a general-purpose computing technology for diagnosis and/or management of a lung or sleep condition using on-board hardware
- Evaluation of AI/ML image pattern recognition tools and for the detection and diagnosis of lung disease
- Mobile health technologies and electronic health records, to target health care provider and/or patient behaviors and/or interactions for promoting adherence to evidence-based guidelines for lung and/or sleep health





Division of Blood Diseases and Resources

Dr. Asif Rizwan 11/02/2022



Division of Blood Diseases and Resources (DBDR)

DBDR is a leader in research on the causes, prevention, and treatment of non-neoplastic blood diseases. DBDR assumes a major responsibility in ensuring the adequacy and safety of the nation's blood supply.

For more information

https://www.nhlbi.nih.gov/about/divisions/division-blood-diseases-and-resources

Follow us on Twitter: @NHLBI_BLOODDir

What We Do

Blood Epidemiology and Clinical Therapeutics

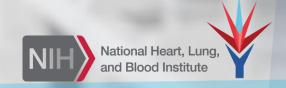
Epidemiologic, clinical, and implementation research throughout the spectrum of blood science.

Molecular Cellular and Systems Blood Science

Physiology and pathophysiology of blood, bone marrow, and blood vessels.

Translational Blood Science and Resources

Therapeutics development and manufacturing, facilitation of discovery science from bench to first-in-human studies.



Division of Blood Diseases and Resources (DBDR)

- Blood diseases impact the normal biology of red and white blood cells,
 platelets, bone marrow, vascular endothelium, and plasma proteins.
- DBDR supports research on
 - benign blood diseases
 - gene therapies, cell therapies such as hematopoietic stem cell transplants
 - transfusion products
 - research to understand the role of blood, bone marrow, and vascular endothelium
 - discovery science from bench to first-in-human studies

DBDR- Examples

Device	Small Molecules and Biologics	Enabling Technologies
Point-of-Care Diagnostic Device	Small Molecule Therapeutics	Proteomics
Microfluidics	Hematopoietic regeneration	Stem Cell Expansion
paper-based device	Iron Overload	Biomarker Discovery
Wearable Sensors	Anticoagulants/antithrombotics	Transfusion
AI/ML powered device	Nuclear-targeting biologic	Gene Editing
Sonothrombolysis	Hemostasis Treatment	Neovascularization
Coagulation monitoring	Hematopoietic regeneration	Coagulation disorders





The Center for Translation Research and Implementation Science (CTRIS) Overview and Priority Areas

George A. Mensah, M.D. Director, CTRIS

November 2, 2022



News & Resources

New NHLBI Center Focuses on Translation Research and Implementation Science

PRESS RELEASES

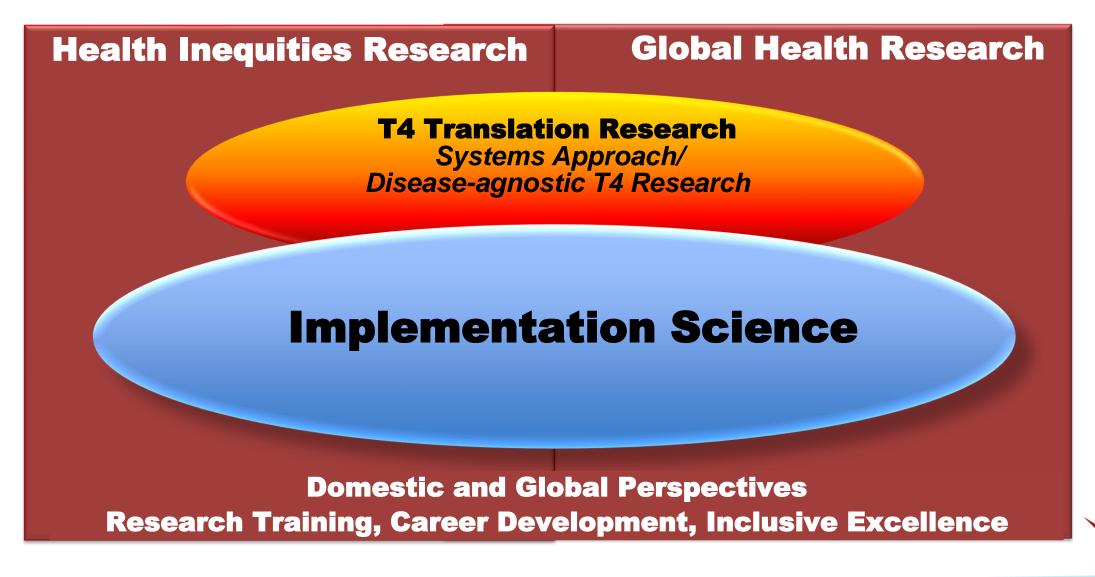


"CTRIS will serve as a strategic focal point for T4 translation research, implementation science, and a research agenda that addresses both domestic and global health inequities, and research training for a workforce to achieve these goals."

CTRIS Announcement January 23, 2014

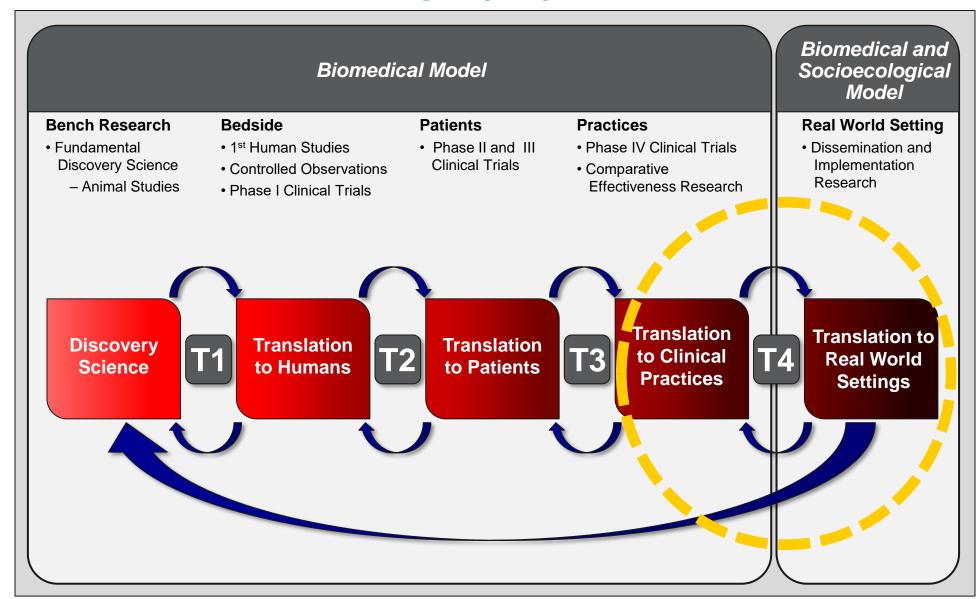


CTRIS Overview and Priority Areas





A Focus on Late-Stage (T4) Translation Research

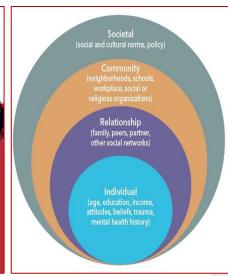


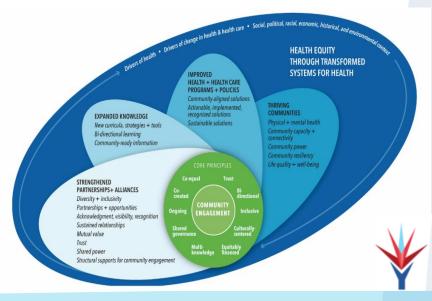


THREE CONTEXTS FOR CTRIS PRIORITIES

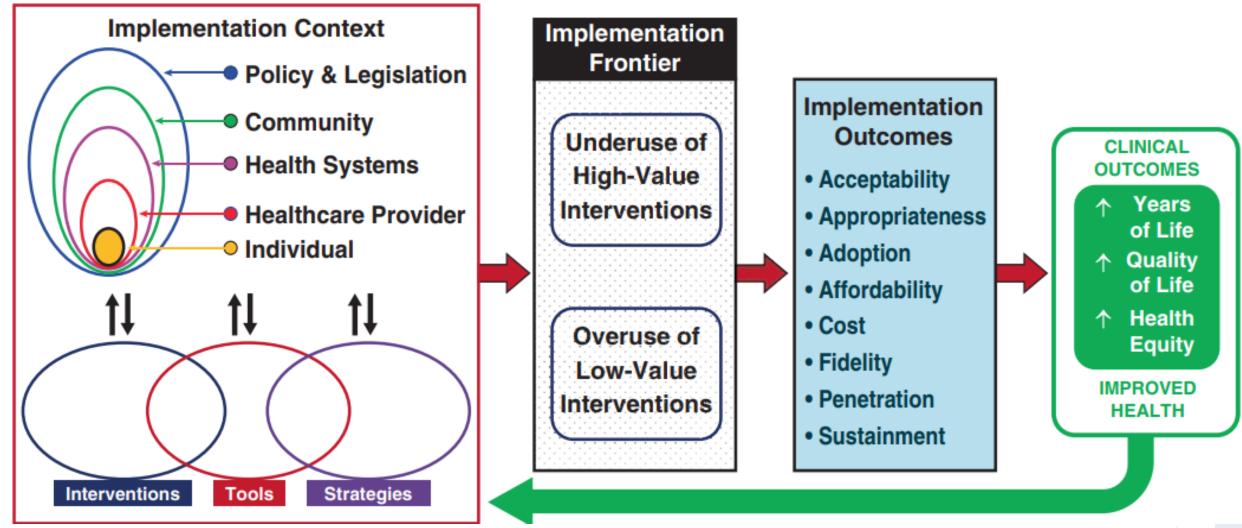
- 1. A focus on individuals as well as on communities, community partners, and community-engaged research with special attention to community-based participatory research (CBPR) and practice-based research network (PBRN) strategies.
- 2. A focus on under-served populations who are disproportionately impacted by heart, lung, blood, and sleep (HLBS) diseases and disorders.
- 3. HLBS priority needs of low- and middle-income countries and low-resource settings in high-income countries. Importance of social & environmental determinants of health.







Important Drivers of CTRIS Priority Areas



Mensah GA (2021). The Implementation Frontier: Chapter 5 in Ferdinand KC, et al. Cardiovascular Disease in Racial and Ethnic Minority Populations https://link.springer.com/content/pdf/10.1007/978-3-030-81034-4.pdf



The CTRIS Executive Team



Jennifer Curry Chief of Staff and Council Liaison



Dave Clark
Chief, Implementation
Science Branch



Xinzhi Zhang
Chief, Health Inequities and
Global Health Branch



Makeda Williams
NHLBI Global Health
Program Director



Desirée SalazarNHLBI DEI Program
Director



George MensahDirector, CTRIS





CTRIS Q&A





Upcoming Events & Reminders

Wednesday November 21st, 2022, 5pm Local Time

Catalyze Applications Due

Stay up to date with us!

Sign up for our email list at nhlbicatalyze.org

Catalyze newsletter, registration links for upcoming webinars, application resources, and important reminders