**Catalyze: Enabling Technologies and Transformative Platforms for HLBS Research** (R33 - Clinical Trials Not Allowed) RFA-HL-26-016

- Applications must offer the potential to accelerate and/or transform the areas of early detection and screening, model development, clinical diagnosis, treatment, control, prevention or epidemiology, while addressing issues associated with HLBS-related diseases and disorders.
- Research Section
  - o Requires milestones, timeline, and project management plan.
  - Requires the identification of team member to serve as project manager.
  - Applicants must include a subsection to describe performance measures.
  - Requires one page attachment describing potential impact.

Catalyze: Product Definition for Small Molecules, Biologics and Combination Products - Target Identification and Validation, and Preliminary Product/Lead Series Identification (R61/R33 – Clinical Trials Not Allowed) RFA-HL-26-017

- The NOFO will provide early-stage translational support needed to identify and characterize
  potential therapeutic candidates (compound and lead series) to treat heart, lung, blood, and
  sleep (HLBS) diseases and disorders.
- Research Section
  - Both R61 and R33 phases require a description of milestones, timeline, performance measures, and project management plan.
  - o Requires the identification of a team member to serve as project manager.
  - Progressing to R33 phase requires identification of at least one Accelerator Partner, provision of evidence of cost match, and continued development of Intellectual Property and regulatory strategies.

Catalyze: Product Definition for Small Molecules, Biologics, and Combination Products - Preliminary Product/Lead Series Identification and Combination Product Prototype (R33 - Clinical Trial Not Allowed) RFA-HL-26-018

- The NOFO will provide early-stage translational support needed for the activities required to develop a lead compound series and combination products to treat HLBS diseases and disorders.
   Research Section
  - Requires a description of milestones, timeline, performance measures, and project management plan.
  - o Requires the identification of a team member to serve as project manager.
  - Contains cost matching component.
  - Requires identification of at least one Accelerator Partner.
  - Requires a separate attachment describing preliminary Intellectual Property and regulatory plans.

## Catalyze: Product Definition – Medical Device prototype design/testing and disease target identification and assay development (R61/R33 - Clinical Trial Not Allowed) RFA-HL-26-019

- The NOFO will provide the early-stage translational support needed to develop and test device
  prototype designs, identify diagnostic disease targets and develop associated assays, and
  develop research tools for use in the treatment of heart, lung, blood and sleep (HLBS) diseases
  and disorders.
- Research Section
  - Both R61 and R33 phases require a description of milestones, timeline, performance measures, and project management plan.
  - o Requires the identification of a team member to serve as project manager.
  - Progressing to R33 phase requires identification of at least one Accelerator Partner, provision of evidence of cost match, and continued development of Intellectual Property and regulatory strategies.

## Catalyze: Product Definition – Medical Device Prototype Optimization (R33 - Clinical Trial Not Allowed) RFA-HL-26-020

- The NOFO will provide the early-stage translational support needed for prototype testing/design modification, assay development for diagnostic disease targets, and development of research tools for use in the treatment of heart, lung, blood, and sleep (HLBS) diseases and disorders. This opportunity is for projects that have already identified and tested initial prototype designs, identified a disease target and generated experimental design, or that identified, tested, and piloted research tools and are further along in the developmental process. Investigators at an earlier stage should explore RFA-HL-26-019.
- Research Strategy
  - Requires description of milestones, timeline, performance measures, and project management plan.
  - o Requires the identification of a team member to serve as project manager.
  - Contains cost match component.
  - Requires at least one Accelerator Partner.
  - Requires a separate attachment describing preliminary Intellectual Property and regulatory plans.