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Preclinical Services Overview

Mike Pieck, Scientific Director
Website: www.nhlbicatalyze.org
Email: NHLBI_catalyze@mail.nih.gov

NIH National Heart, Lung, and Blood Institute

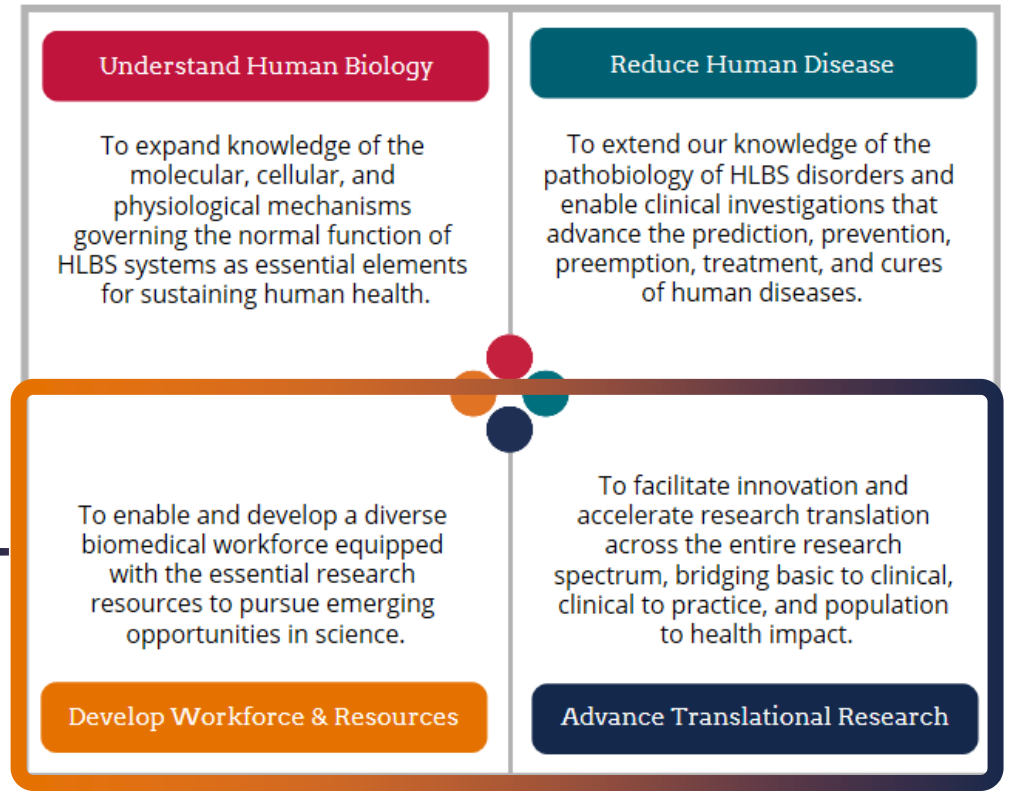
Background

NHLBI Catalyze Program

Provide a bridge from basic to clinical research across the entire Heart, Lung, Blood, Sleep research spectrum

Train a diverse scientific workforce fluent in both product development and entrepreneurship

NHLBI Strategic Vision



NHLBI Strategic Vision: https://www.nhlbi.nih.gov/about/strategic-vision/goals-and-objectives

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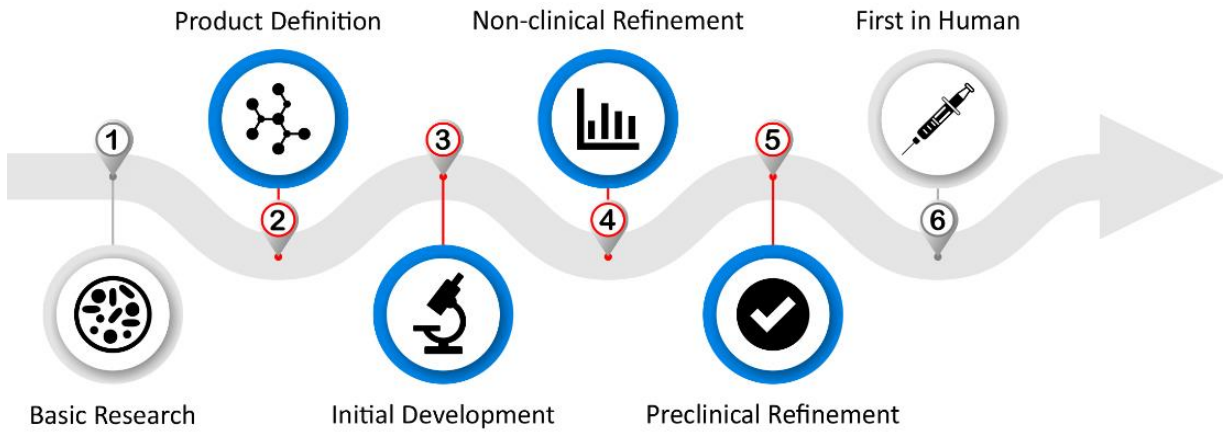
Strategy



Funding

Leverage NHLBI investment with matching commitments and flexibility

Coordinated approach

Seamless continuum of programs from product definition to first-in-human trials

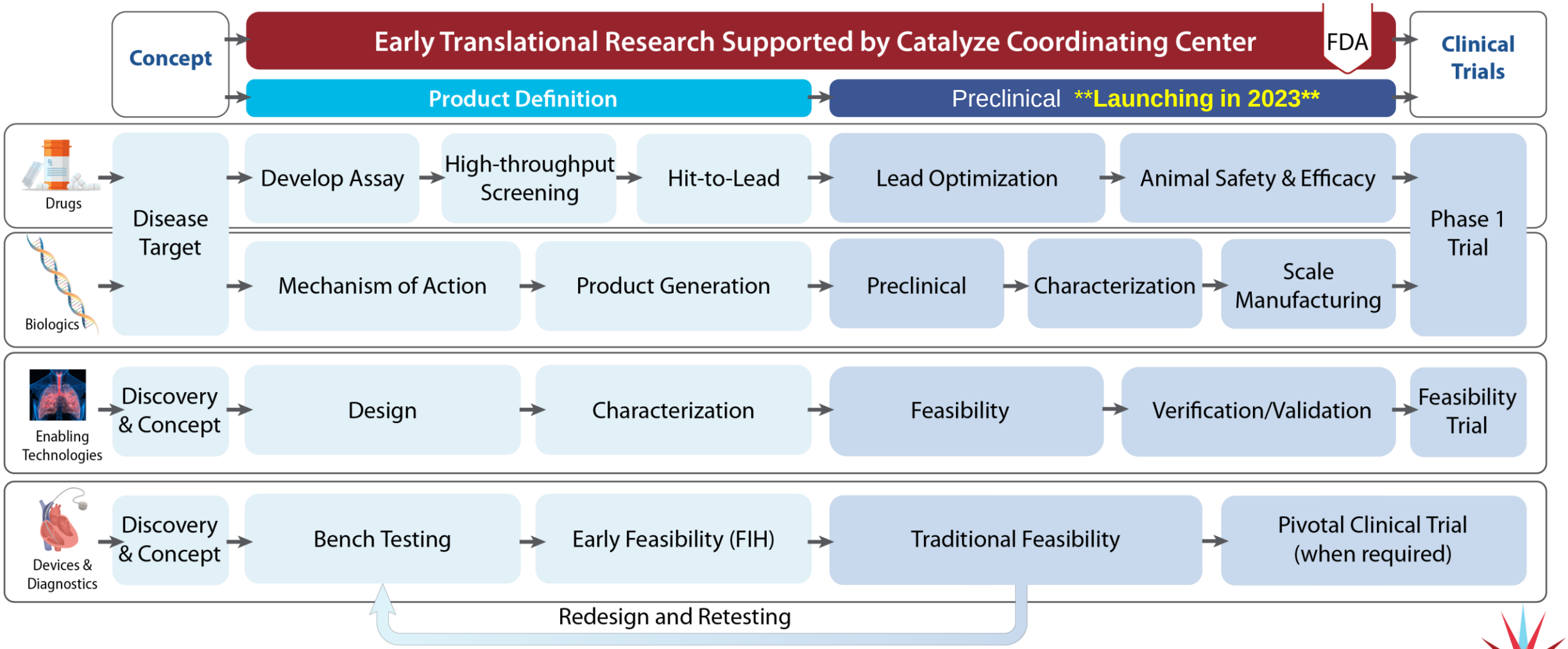
Individualized support

Milestone-driven project management and support to mitigate technical risk

Program flexibility

Early identification of trends and challenges across the program (pivot when needed) and disseminate lessons-learned

Program Components



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

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Product Definition Funding Opportunities

Application Deadlines
February 21 | July 21 | November 21

Enabling Technologies

$300K direct cost / yr.

- Enabling Technologies and Transformative Platforms for HLBS Research *R33* (RFA-HL-23-010)

Small Molecules and Biologics

$350K direct cost / yr.

- Target Identification and Validation, Preliminary Product/Lead Series Identification *R61/R33* (RFA-HL-23-011)
- Preliminary Product/Lead Series Identification *R33* (RFA-HL-23-012)

Devices and Diagnostics

$250K direct cost / yr.

- Protype Design and Testing, Diagnostic Disease Target Identification, Assay Development and Research Tool Dev. *R61/R33* (RFA-HL-23-013)
- Prototype Testing and Design Modification, Diagnostic Disease Target Assay Development, and Design Characterization, and Research Tool Testing and Validation *R33* (RFA-HL-23-014)

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Catalyze CC Resources

Product Development Support

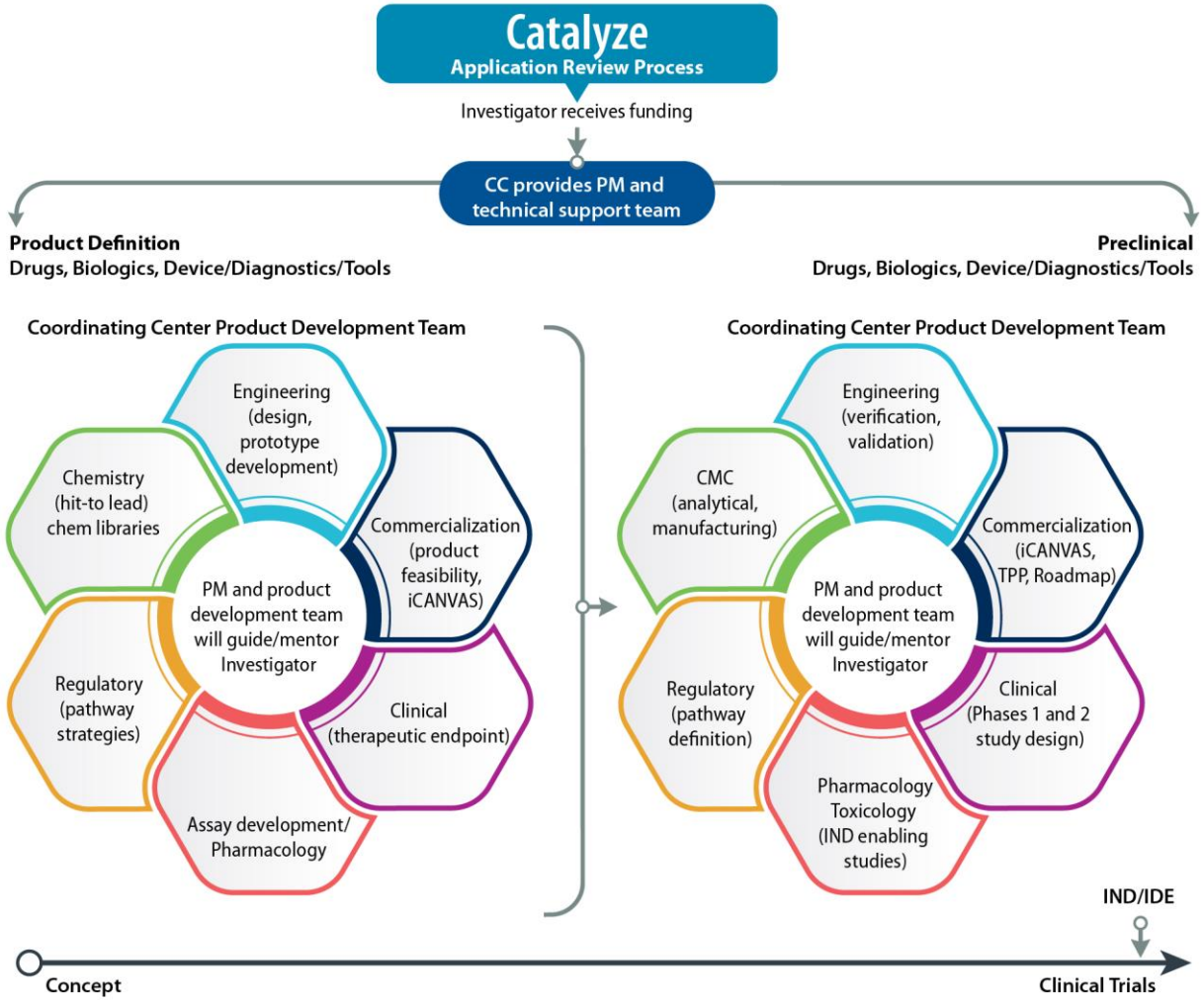
- Therapeutics
  - Chemistry
  - Pharmacology
  - Assay development
  - Toxicology
- Engineering support
  - Prototype development
  - Design verification and validation
- Regulatory Affairs
  - Strategy development
  - FDA Submissions

Commercialization Support

- Technology readiness
- Feasibility
- Intellectual property

Skills Development

- Courses, workshops



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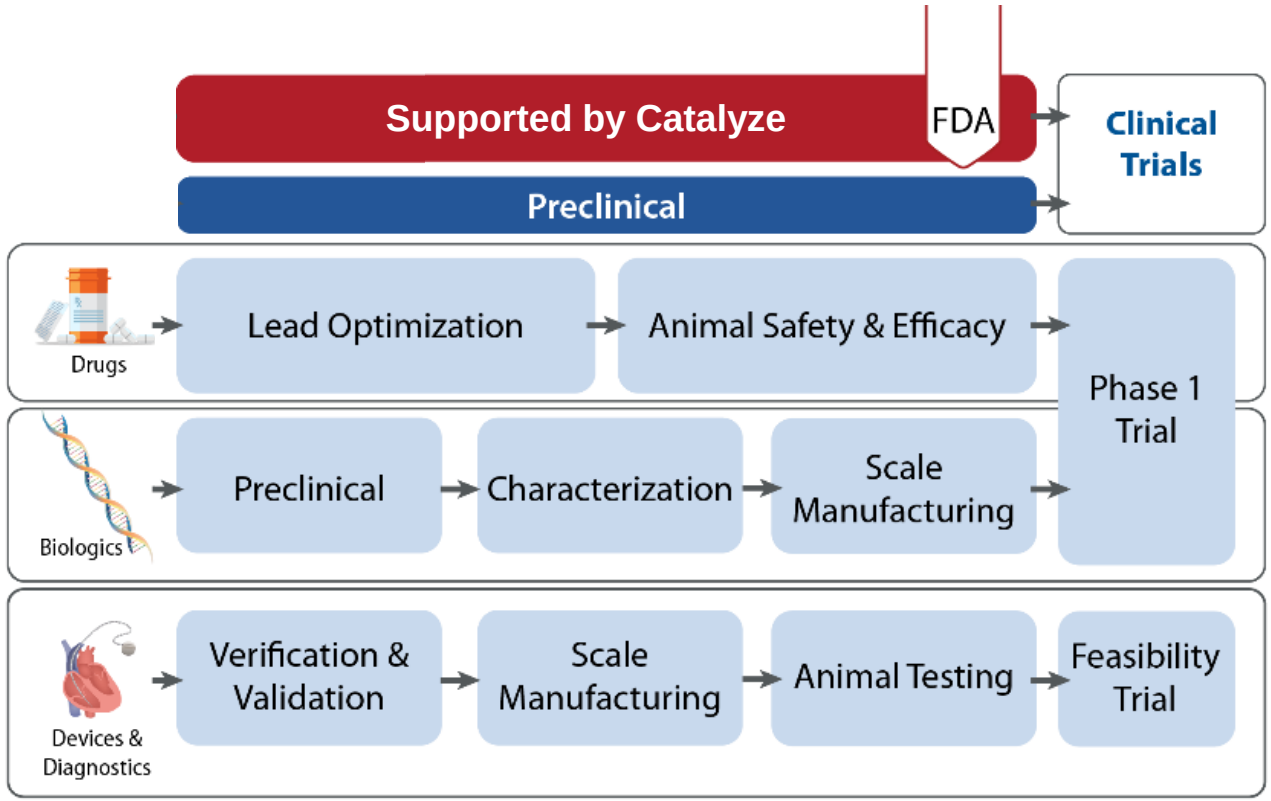
Catalyze Preclinical Services Implementation *2023*



- Simple online application to request services (EOI, full application)
- Focus on gap filling studies to accelerate promising technology toward traditional funding mechanisms or 3rd party investment
- Applicants will be expected to achieve commercial milestones in exchange for preclinical services

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

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Target Criteria for Preclinical Services

Small Molecules

- Modulation of the target has a desired outcome for Heart/Lung/Blood/Sleep (HLBS) indication

- **No more than three putative lead compounds** with proof of identity, purity, selectivity, and activity, **with a single lead** to be selected during the project

- Demonstration of in vivo efficacy by desired route of administration in a model relevant to the chosen HLBS indication.

- Preliminary absorption, distribution, metabolism, excretion, toxicity (ADMET) and bioavailability data

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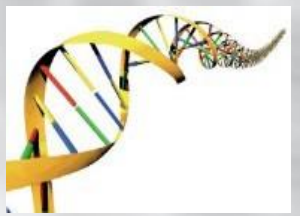
Target Criteria for Preclinical Services



Biologics

- Demonstration of in vivo efficacy by desired route of administration in a model relevant to the chosen HLBS indication

- Quantitative profiles (selectivity, stability, other relevant modality-specific characteristics) to provide justification for **no more than two agents** for further development, **with a single agent** to be selected during the project

- Documentation of the source material (e.g., master cell bank, plasma, bone marrow, etc.)

- Preliminary ADMET and bioavailability data

- Preliminary data related to manufacturability, including reproducible production

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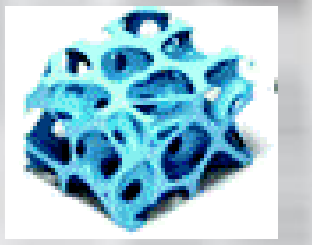
Target Criteria for Preclinical Services



Tissue Engineered Products

- Biodegradability and biocompatibility testing (ISO10993)
- Preliminary cell characterization (to include sterility and bioburden testing)
- Scaffold architecture prototype definition and mechanical property testing
- Preliminary manufacturing technology (GMP, shelf-availability)

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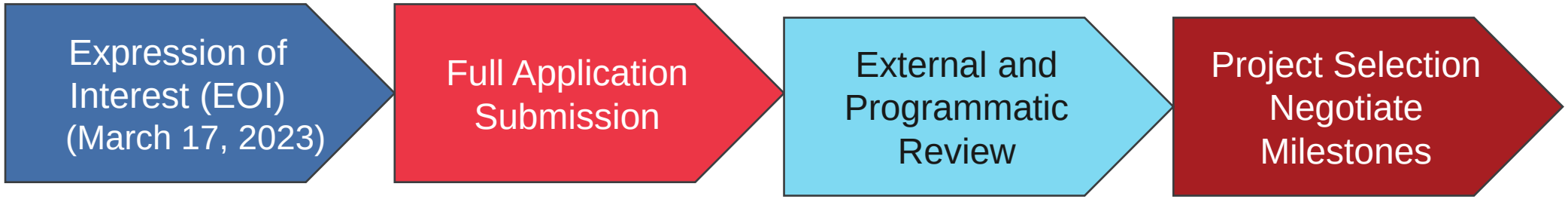
Target Criteria for Preclinical Services

Devices

- In vitro device safety and efficacy tests (e.g., biocompatibility, durability, and performance testing)
- Validation and verification testing of protype complete
- Design History File created and updated regularly
- In vivo safety and efficacy tests
- Computational modeling analyses (e.g., computational fluid mechanics, finite element analysis) of final design
- Device packaging, shelf life, aging, and sterilization studies
- Device human factors/usability testing
- Risk/Hazard Analysis and design of a Risk Management process

Preclinical Services Application Process



- All EOIs will receive notification from Catalyze CC
- Selected EOIs will have 30 days to complete the full application
- Top scoring applicants may be expected to present a pitch to NHLBI Catalyze Steering Committee and NHLBI Commercialization Review Board
- Project selection and services are subject to funding availability

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Preclinical Services Application Process

Expression of Interest (EOI)

Submit by March 17, 2023

- Section 3: Technology Profile
  - Provide basic information on your technology
  - Indicate services you are requesting
    - Preclinical studies/CMC/Manufacturing
    - Regulatory Affairs
  - Brief description of IP
- **All EOI submission will receive response from Catalyze CC**
- **Select # of EOIs will be invited to submit a full application**

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Preclinical Services Application Process

Full Application

30-day submission window

- **Section 4: Prior Technology Development**
  - Describe prior NIH grant or other funding
- **Section 5: Basis for Project**
  - Preliminary technical data
  - Unmet need, Market landscape
  - Commercialization Strategy
  - Regulatory and IP Strategy
- **Section 6: Project Plan**
  - Describe the current state of your technology and what steps are needed to achieve FDA clearance and define your product development plan for market approval
  - Description of key go/no-go milestones for preclinical services requested
  - Brief bio-sketch of team members
  - External partnerships

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Preclinical Services Application Process

Full Application
Items to prepare now

- **Review PDF version and prepare answers for web-based form**
- **Quote from US-based CRO/CMO or Vendor**
  - Ideally a quote within the past 3 months
  - Covers the activities requested from Catalyze
  - Helps the NHLBI identify scope and budget of proposals
- **Investor Pitch Deck**
  - Will be used as part of the review
  - Reference: NHBLI Catalyze Webinar: Preparing and Delivering Effective Pitches
- **Letters of Support**
  - Accelerator Partner
  - Non-federal funding from last 12 months and any future commitments

Expectations for Awardees

- Awardees will be expected to achieve negotiated commercial milestones
- Opportunity to work with Catalyze Coordinating Center's Innovation Advisors
- Access to NHLBI team of EIRS (Investment, IP, Regulatory, Clinical trial design, Reimbursement)

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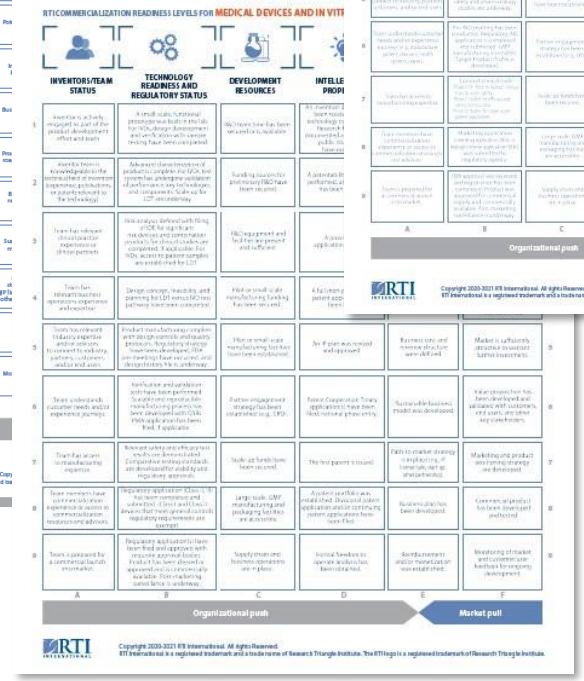
Drugs & Biologics



Medical Devices & In Vitro Diagnostics

[NHLBI Catalyze Webinar: Beyond Technical Milestones - Incorporating Desirability Into Your Innovation]

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Q&A

NHLBI Catalyze Information

- **Catalyze Preclinical Services**
  - Expression of Interest: Closes March 17, 2023
  - Quote from a US-based CRO/CMO within the last 3 months is recommended

- Eligibility: US academic, non-profit and for-profit institutions
  - NHBLI Catalyze FAQ page (https://nhlbicatalyze.org/faq)

- Website: https://nhlbicatalyze.org
- Email: NHLBI_catalyze@mail.nih.gov

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