



Preclinical Services Overview

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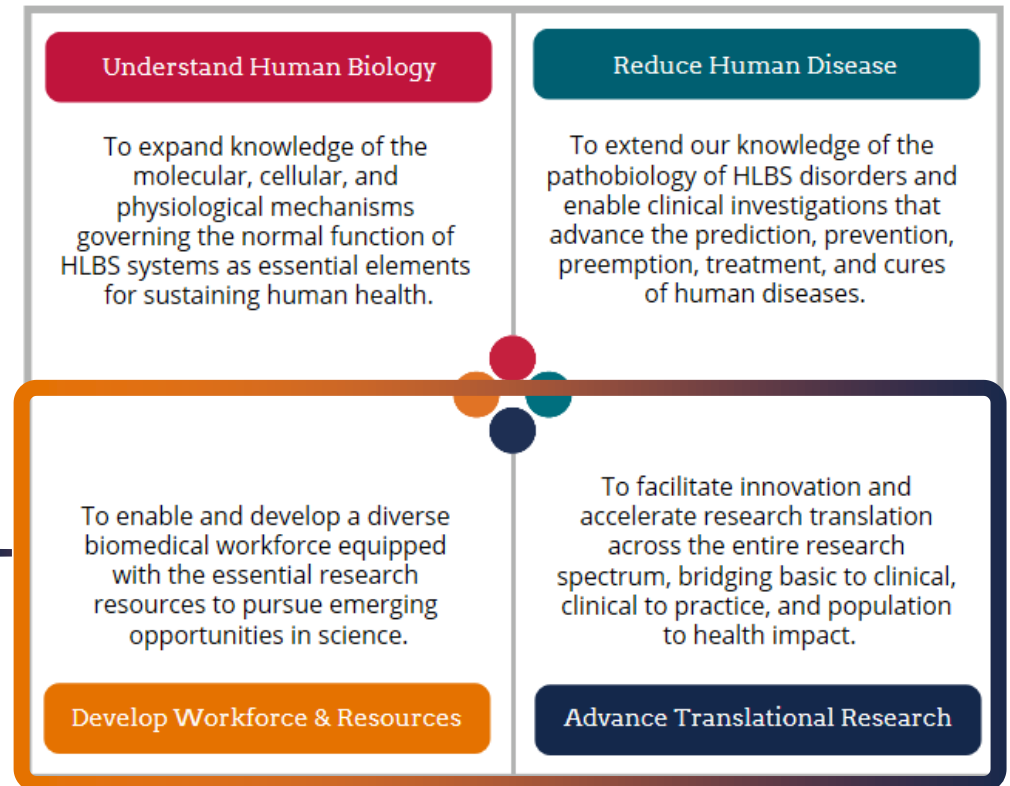
National Heart, Lung,
and Blood Institute

NHLBI Catalyze Program

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

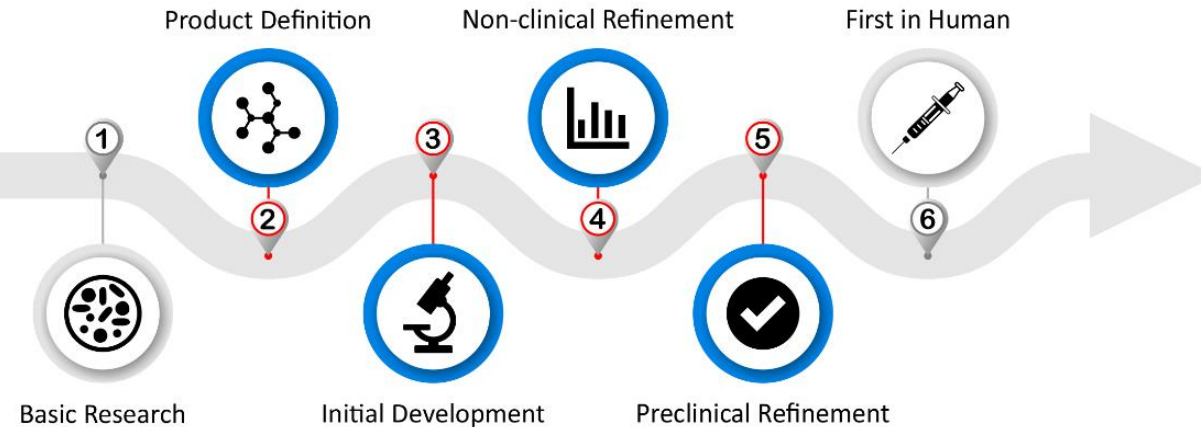
Train a diverse scientific workforce fluent in both **product development** and **entrepreneurship**

NHLBI Strategic Vision





Strategy



Funding

Leverage NHLBI investment with matching commitments and flexibility

Coordinated approach

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

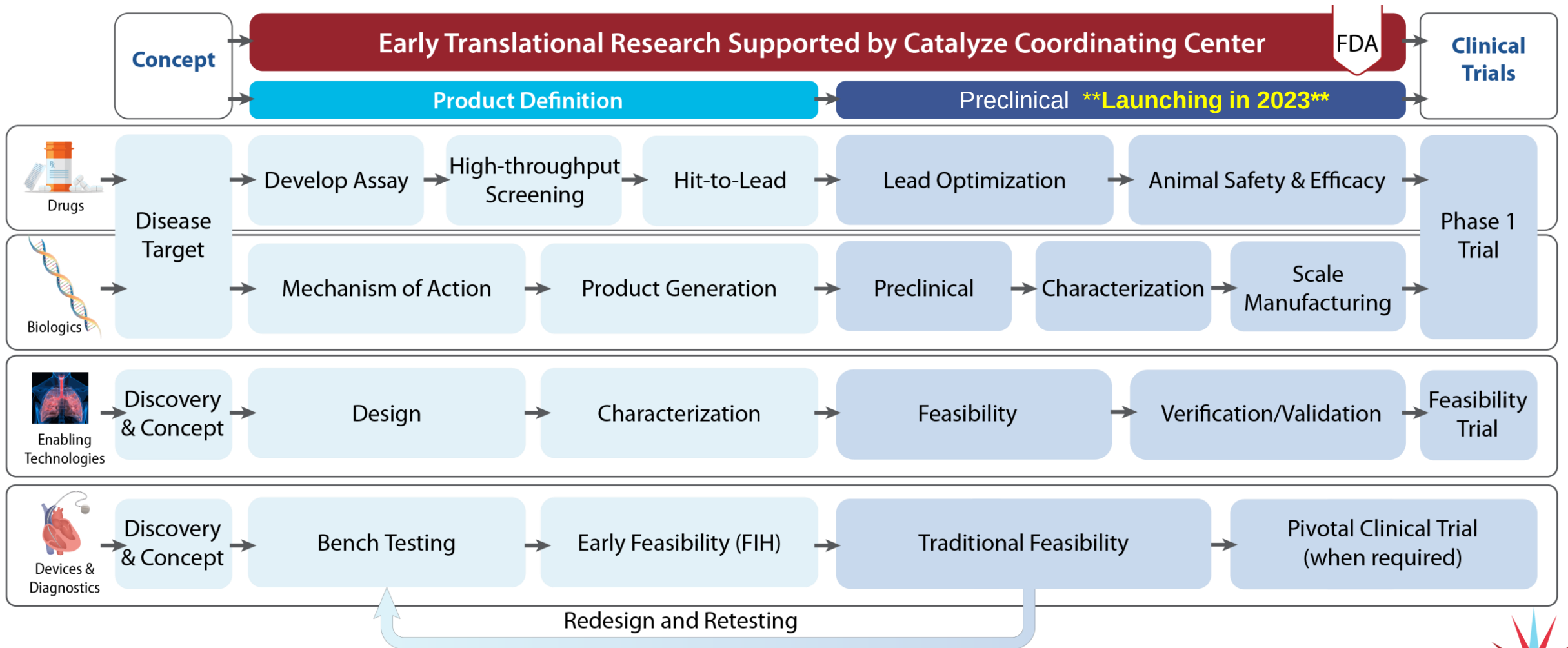
Individualized support

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



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.

- Prototype 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

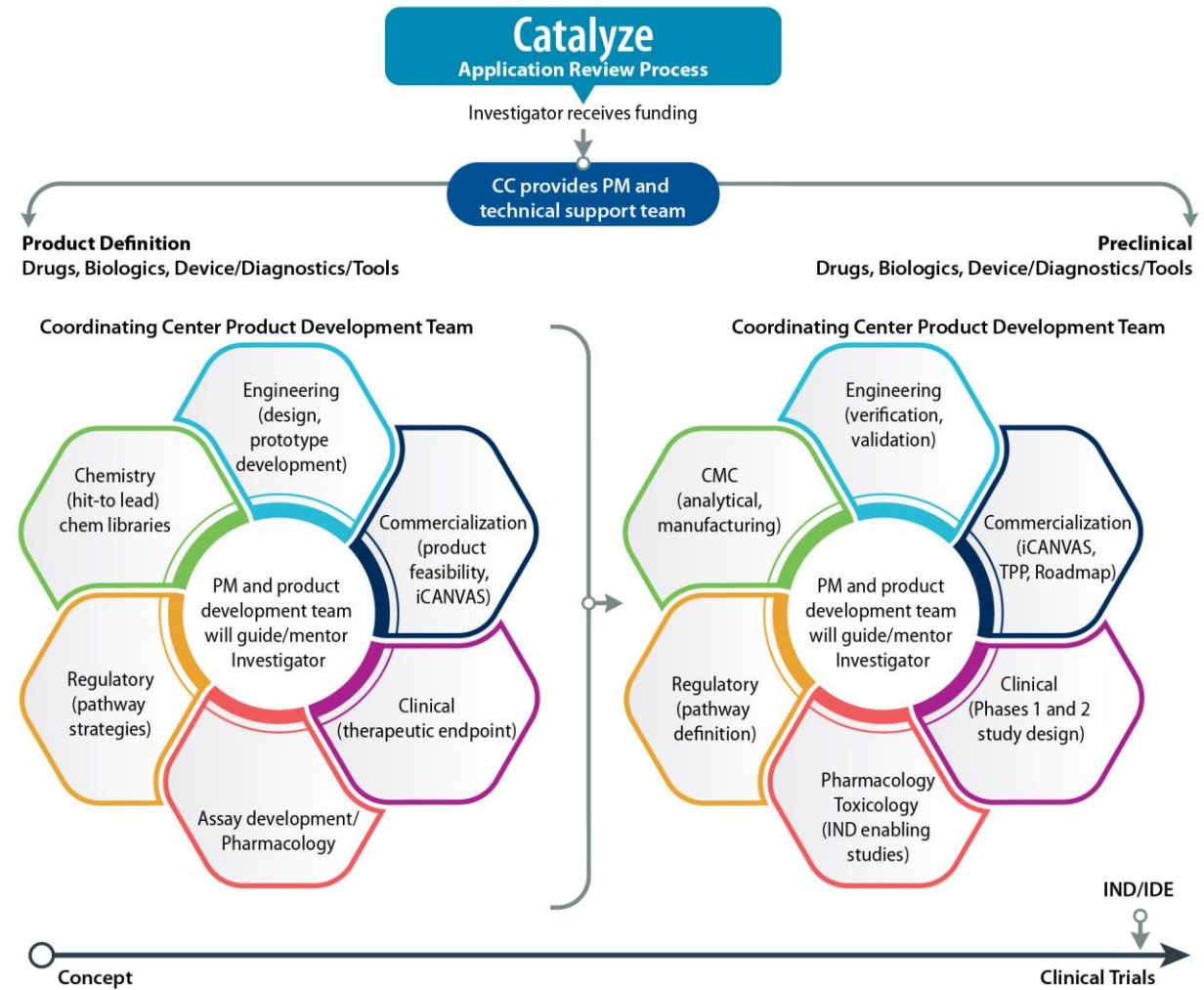
- Therapeutics
 - Chemistry
 - Pharmacology
 - Assay development
 - Toxicology
- Engineering support
 - Prototype development
 - Design verification and validation
- Regulatory Affairs
 - Strategy development
 - FDA Submissions

Commercialization Support

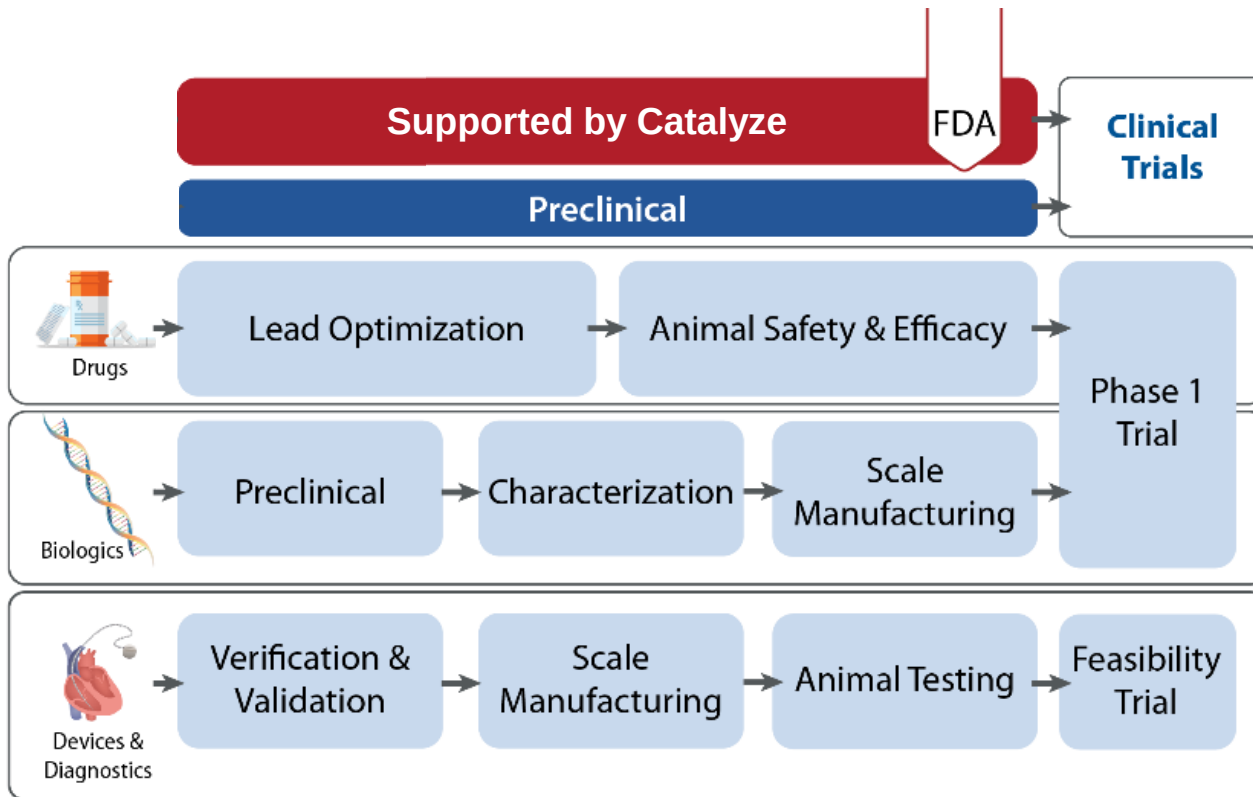
- Technology readiness
- Feasibility
- Intellectual property

Skills Development

- Courses, workshops



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



Target Criteria for Preclinical Services

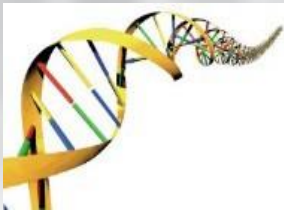


Small Molecules

- 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



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



Target Criteria for Preclinical Services

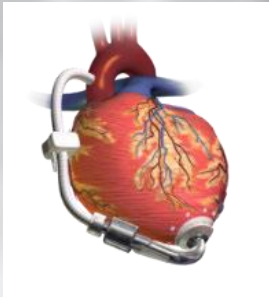


Tissue Engineered Products

- 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)



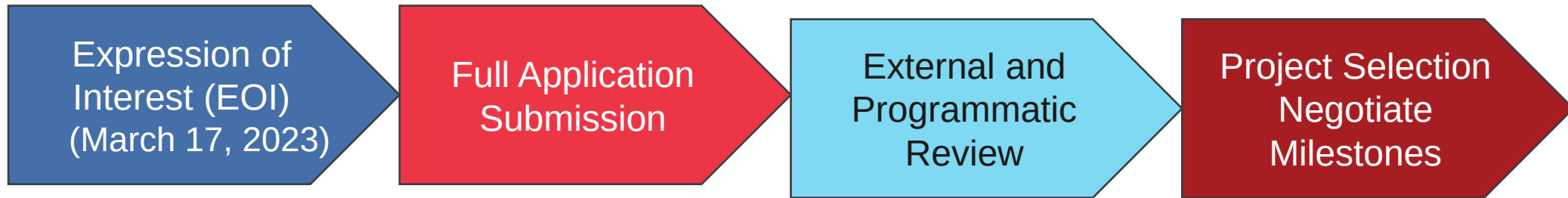
Target Criteria for Preclinical Services



Devices

- In vitro device safety and efficacy tests (e.g., biocompatibility, durability, and performance testing)
- Validation and verification testing of prototype 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





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**



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



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)

RTI's ICANVAS®

Novel Research Technologies

RTI COMMERCIALIZATION READINESS LEVELS FOR NOVEL RESEARCH TECHNOLOGIES

INVENTORS/TEAM STATUS	TECHNOLOGY READINESS AND REGULATORY STATUS	DEVELOPMENT RESOURCES	INTELLECTUAL PROPERTY	BUSINESS STRATEGY	MARKET FIT
0	Inventors are listed on the technology disclosure form.	General feedback is available.	An invention disclosure is required by the technology transfer office.		
1	Inventor is actively engaged as part of the technology transfer effort and team.	Basic research is conducted, preliminary experimental data are obtained.	Research is documented and no known public disclosure has occurred.		
2	Team members have publications or patents related to the technology.	The technology concept and application are formulated.	A patentability search is performed, and a pre-plan is drafted.		
3	Team has technical talent to drive product development.	R&D has begun, first lab test are completed and positive.	Developing funds secured.	A pre-clinical application is filed.	
4	Team has additional talent to commercialize the technology.	A small scale prototype is built in lab.	Prototyping facilities are available.	A full (non-pre-clinical) patent application is filed.	
5	Team has business expertise.	A large scale prototype is built in a relevant environment.	Prototyping facilities are available.	Further engagement strategy is established.	An IP plan is revised and approved.
6	Team has industry support in the technology domain.	A prototype system is built in a relevant environment.	Scale-up funds are secured.	Patent Cooperation Treaty (PCT) application is filed, national phase entry.	
7	Team has a customer base.	A demonstration system performs in a relevant environment.	Large scale manufacturing and packaging facilities are available.	The first patent is issued.	
8	Team members have commercialization experience.	The final commercial system is built, and all manufacturing issues are solved.	Supply chain operations are in place.	A patent portfolio strategy is established, additional patent applications are filed.	
9	Team is scale-ready.	The product is available for commercial applications.	Business operations are in place.	Patent freedom to operate analysis is obtained.	

RTI is required to

Drugs & Biologics

RTI COMMERCIALIZATION READINESS LEVELS FOR DRUGS AND BIOLOGICS

INVENTORS/TEAM STATUS	TECHNOLOGY READINESS AND REGULATORY STATUS	DEVELOPMENT RESOURCES	INTELLECTUAL PROPERTY	BUSINESS STRATEGY	MARKET FIT
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RTI is required to

RTI COMMERCIALIZATION READINESS LEVELS FOR MEDICAL DEVICES AND IN VITRO

INVENTORS/TEAM STATUS	TECHNOLOGY READINESS AND REGULATORY STATUS	DEVELOPMENT RESOURCES	INTELLECTUAL PROPERTY	BUSINESS STRATEGY	MARKET FIT
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Medical Devices & In Vitro Diagnostics

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

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) (<https://nhlbicatalyze.org/faq>)
- Website: <https://nhlbicatalyze.org>
- Email: NHLBI_catalyze@mail.nih.gov