Successfully Navigate Regulatory Pathways to Get Your Products to Market

Customer Experience Hub Members are invited to the Monthly Meeting on Thursday, November 21, at 11:30 a.m. CT / 12:30 p.m. ET to learn successful strategies for securing medical product approval in today's complex regulatory environment.

We are excited to welcome Barry Sands, president and founder of **RQMIS**, who will present *Navigating the Regulatory Application Process for Medical Products*. With his deep understanding of the complex and ever-evolving regulatory landscape, Barry will outline strategic approaches to regulatory applications, address key compliance challenges, and give an overview of navigating key regulatory bodies and processes as you bring your products to market.

Sign up now for this member only event: **https://bit.ly/3Ci6QNd**

CATALYST to develop predictive drug safety and efficacy models for new drug candidates

ARPA-H has released a new funding opportunity through its Computational ADME-Tox and Physiology Analysis for Safer Therapeutics (**CATALYST**) program. CATALYST

intends to create human physiology-based computer models to accurately predict safety and efficacy profiles for Investigational New Drug (IND) candidates.

Current clinical drug development can be a long, expensive, and inefficient. Creating more accurate preclinical safety and efficacy assessments could help lower drug costs and increase orphan drug development.

CATALYST envisions a future where approval to begin first in-human clinical trials can be based on *in silico* safety data. **Program Manager Andy Kilianski, Ph.D.**, states, "CATALYST seeks to transform how we predict clinical effects and will support the adoption of these novel drug development tools for use in regulatory science. CATALYST's predictive tools will break through these bottlenecks by designing better *in silico* models and demonstrating their effectiveness in preclinical studies. This leads to more representative safety assessments, shorter development timelines for orphan drugs, less expensive therapies, and better patient safety for all."

CATALYST invites proposals across three technical areas: data discovery and deep learning methods for drug safety models, living systems tools for model development, and *in silico* models of human physiology.

Solutions summaries are due November 25, 2024, 5:00 p.m. ET.
Submit your best solutions today:
https://sam.gov/opp/325e7a5a97124b6b9b4916818e88cb91/view

ARPA-H Program News and Dates

ARPA-H is conducting market research on next-generation Agentic Artificial Intelligence (AI) systems and their potential applications to accelerate better health outcomes for everyone. This Request for Information (RFI) seeks to enhance ARPA-H's understanding of the Agentic AI landscape.

Response Date: November 29, 2024, 4:00 p.m. ET

View the full RFI (75N992-25-RFI-106) and submission instructions: **Agentic Artificial Intelligence (AI) for Health care**.

A funding opportunity through the Ocular Laboratory for Analysis of Biomarkers (**OCULAB**) program seeks to develop a tear-based biomarker measurement system that can be inserted into the tear duct for continuous health monitoring and provide ultra-precise medication dosing for personalized treatment via a closed-loop delivery system.

Solution Summaries due: January 27, 2025, 5:00 p.m. ET

Welcome New Spokes!

Let's welcome our newest members:

Landmark Bio PBLLC
LastMinute, Inc.
Netrias LLC
The Susan G. Komen Breast Cancer Foundation, Inc.
Access Pediatric LLC
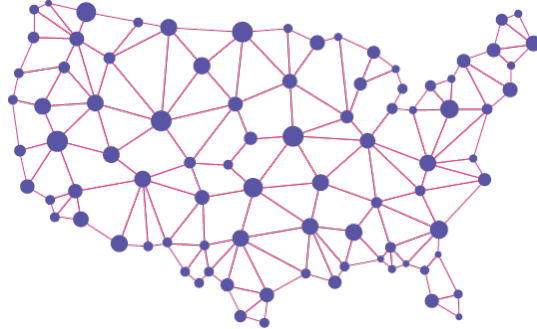Advanced Telesensors, Inc.
Biogenesis
ELHS Institute, Inc.
Performance Hypothesis LLC

Know of any potential spokes? Connect them to us by sending them our **website**, or contacting us at
arpa-h-cx-hub@ati.org

View all ARPA-H Programs

Stay Engaged with Network Resources

Events Calendar

Have an upcoming event you'd like other spokes to attend and us to advertise? **Submit your event** to have it featured across our websites and social channels.

Spoke Member Portal

Your gateway to seamless collaboration and amplified engagement is here! Spokes, **log in** today to post questions, showcase your specialized skills, and more.

Office Hours

Sign up to learn more about Customer Experience Hub open opportunities, member resources, and the benefits of being a spoke!

To stay up to date on the latest ARPA-H News, subscribe to **ARPA-H ARPA-H Vitals**.