



Monthly Virtual Meeting

December 2023

Agenda



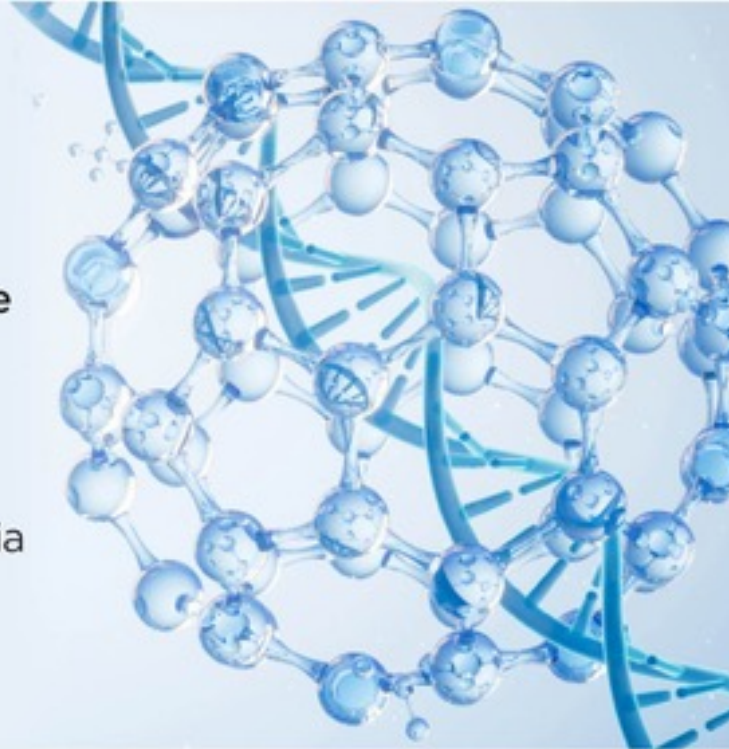
- Welcome and Introductions
- Upcoming Events & Activities
- Spoke Membership Information
- Andrew Kilianski, Ph.D., ARPA-H Program Manager
- Q & A Session

Upcoming Events

42nd Annual
J.P. Morgan Healthcare
Conference

January 8-11 2024

San Francisco, California




Spoke Members, Submit Your Event



ACA 2024
The Summit of Angel Investing
May 13 - 15, 2024 

The Summit of Angel Investing
May 13 -15, 2024
Columbus, Ohio



FoundHer Stories | A Fireside Chat with
Tina Boville

Spoke Application

Who Can Apply?

The opportunity to apply to become a spoke is open to all institutions/organizations with strengths that align with the ARPA-H research focus areas:

- Health Science Futures: Expanding what is technically possible
- Proactive Health: Keeping people from being patients
- Scalable Solutions: Reaching everyone quickly
- Resilient Systems: Building integrated healthcare systems



Spoke Benefits



Spokes are eligible to **apply for funding** to support Investor Catalyst activities, projects, immersive experiences, and initiatives.



Spokes are able to use **flexible contracting vehicles** resulting in award execution significantly faster than traditional government contracts.



Spoke membership provides **networking opportunities** with consortium members (industry, academia, nonprofits, and other health ecosystem stakeholders), government (ARPA-H and other federal agencies) and other strategic stakeholders at annual membership meetings, conferences, and forums.



Spokes have opportunities to provide **feedback and input** into ARPA-H challenge areas, problem identification, and priorities.



Spokes will also be able to access and contribute to an open **library of resources** and public goods that draw on the insights from ARPANET-H activities.

Frequently Asked Questions

- If an organization becomes a member of the IC Hub, does that have any bearing on their potential ability to apply for or receive funding through ARPA-H funding programs or BAAs?
- What are the programs we can get involved in through the Investor Catalyst Hub and when will they be announced?



ARPANET-H 2024 Activities

- 1. R&D Funding Opportunities:** ARPA-H funding opportunities issued through the hub.
- 2. Network Activations:** ARPA-H crowdsources feedback on problems or questions by drawing on the skills and reach of the network. This feedback helps shape possible funding opportunities.
- 3. Network Events:** Interact with ARPA-H Program Managers to learn about our research priorities, engage with other network members—both virtually and in-person—and participate in other programming.

Contact Us

Visit us at <https://investorcatalysthub.org>

Email us at arpa-h-ic-hub@venturewell.org



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The ARPA-H Model: *Transforming Health for All*

Antigens Predicted for Broad Viral Efficacy through Computational Experimentation (APECx)

Advanced Research Projects Agency for Health (ARPA-H)

Andrew Kilianski, PhD

Program Manager

Health Science Futures (HSF) Mission Office

December 21, 2023



Mission

Accelerate better
health outcomes
for everyone.



President Biden's Vision

"ARPA-H will **pursue ideas that break the mold on how we normally support fundamental research and commercial products** in this country."

"Ideas so audacious that people say they just might work only if, only if, we could try. Well, we're about to try in a big way."

– President Biden Remarks, March 18, 2022

DELIVERING BIPARTISAN PROGRESS
THROUGH PRESIDENT BIDEN'S UNITY AGENDA

- ✓ Made it easier for doctors to prescribe effective treatments for opioid addiction
- ✓ Passed a gun safety law making historic investments in youth mental health
- ✓ Launched ARPA-H to drive breakthroughs in the fight against cancer, Alzheimer's, and diabetes
- ✓ Expanded benefits and services for veterans and their survivors

WH.GOV/SOTU



JULY 27, 2023

As Part of President Biden's Unity Agenda, Cancer Moonshot Announces Launch of New ARPA-H Program to Develop Novel Technologies for More Precise and Accurate Cancer Tumor Removal

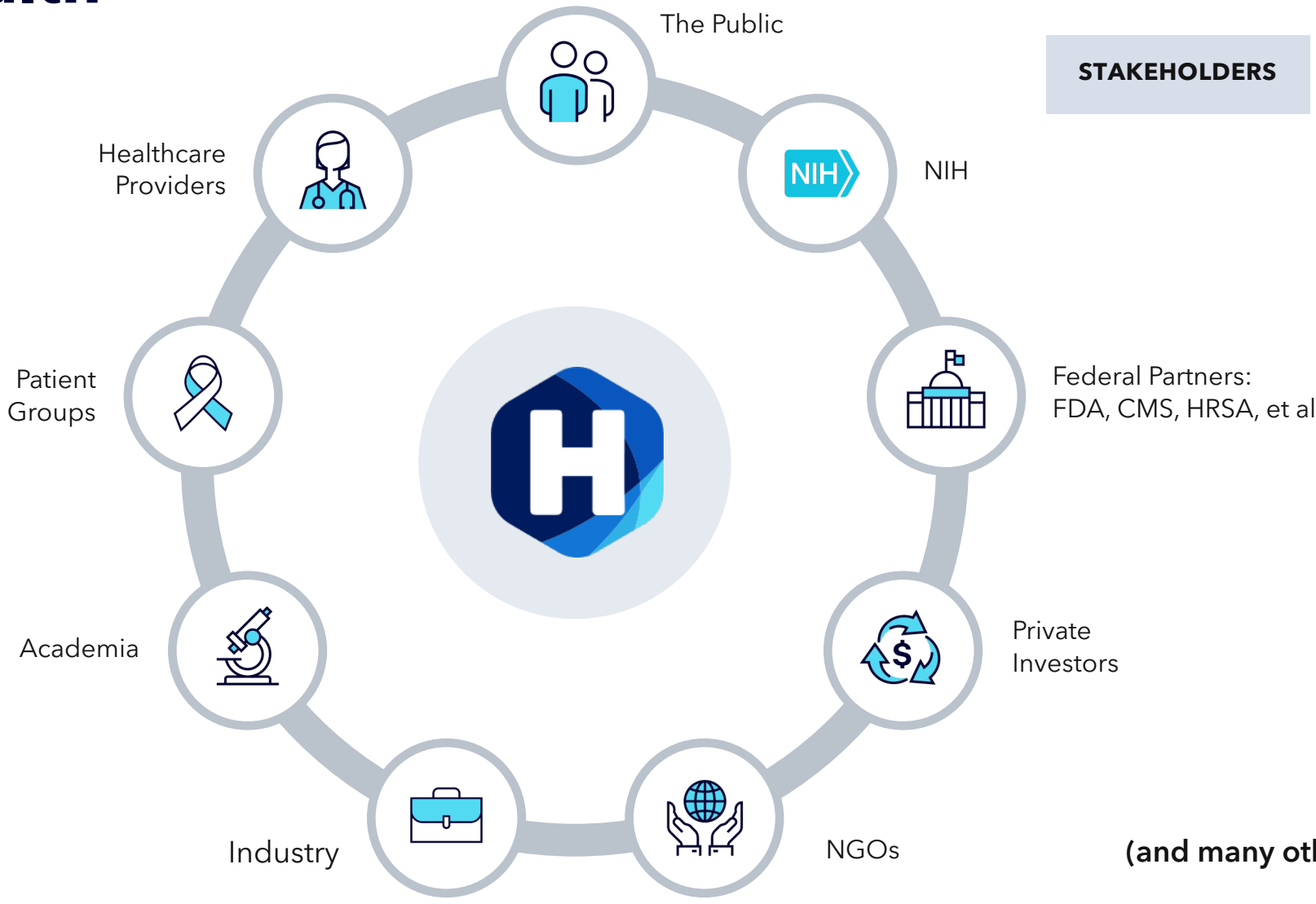


ARPA-H Health Ecosystem

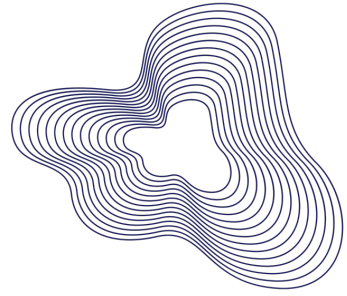
CUSTOMERS

PERFORMERS

STAKEHOLDERS



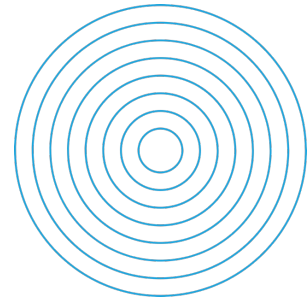
Initial Mission Focus Areas



Health Science Futures

Expanding what's technically possible

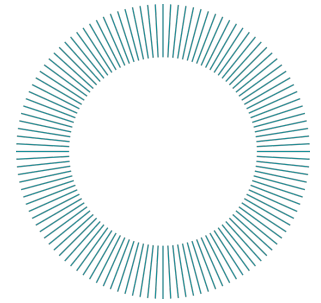
Accelerate advances across research areas and remove limitations that stymie progress towards solutions. These tools and platforms apply to a broad range of diseases.



Scalable Solutions

Reaching everyone quickly

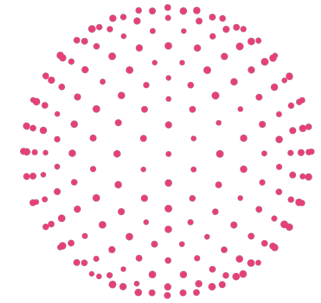
Address health challenges that include geography, distribution, manufacturing, data and information, and economies of scale to create programs that result in impactful, timely, and equitable solutions.



Proactive Health

Keeping people from being patients

Preventative programs will create new capabilities to detect and characterize disease risk and promote treatments and behaviors to anticipate threats to Americans' health, whether those are viral, bacterial, chemical, physical, or psychological.



Resilient Systems

Building integrated healthcare systems

Develop capabilities, business models, and integrations to endure crises such as pandemics, social disruption, and economic instability. Resilient systems need to sustain themselves between crises—from the molecular to the societal—to better achieve outcomes that advance American health and wellbeing.

ARPA-H Model: Support and Evaluation

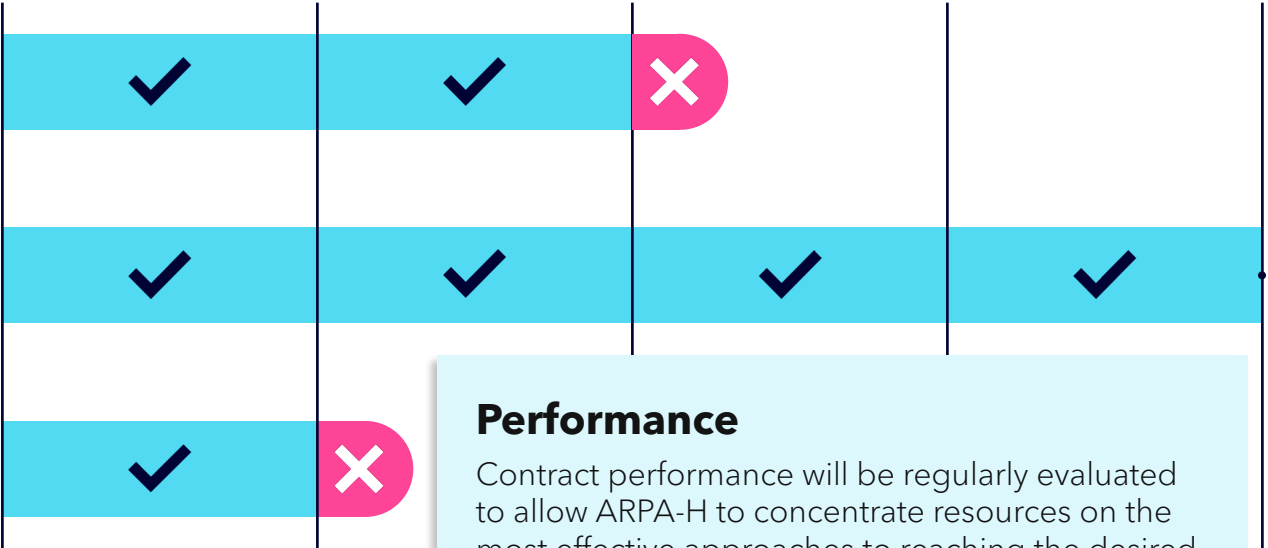


Support

ARPA-H will provide contracts - not grants - for projects with well-defined endpoints. Additional support will be provided by Program Managers, partners, and ARPA-H offices to ensure the best chance of success throughout the process.



Performer
Performer
Performer



Focus Areas

Unlock new ways to collaborate and attack problems



Health Science Futures

Expand What's Technically Possible

Develop approaches that bring radically new insights and paradigms. These **innovative tools, technologies, and platforms** can apply to a broad range of diseases that affect large populations, rare diseases, or diseases with limited treatment options.

Examples include:

- Novel molecular platform approaches
 - Modulation of host systems
 - Delivery to targets with spatial and temporal precision
 - Mitigation of off-target effects to accelerate interventions
- Approaches to accelerate mammalian and microbial cellular engineering to enable next generation therapeutic applications
- Interventions that target and reverse disease pathogenesis or enhance plasticity to address degenerative diseases
- Advances in genetic, cellular, tissue, and organ replacement therapies

First Programs Launch!

NITRO: Novel Innovations for Tissue Regeneration in Osteoarthritis

Program Overview

VISION: Eradicate osteoarthritis (OA) through **targeted, regenerative therapeutics** that will revolutionize the care algorithm, prevent pain, decrease the economic burden, and eliminate the need for repeat joint surgery with equitable access for all Americans.

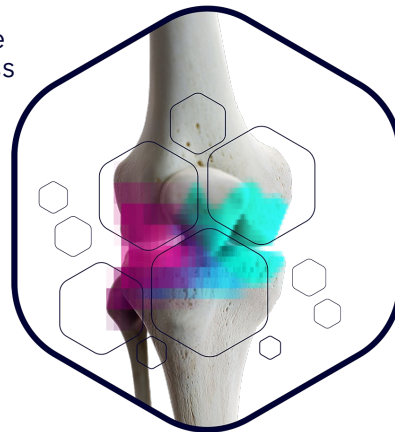
Technology focus areas

- Needle-based and/or non-invasive bone regeneration
- Needle-based and/or non-invasive cartilage regeneration
- Replacement joints built from human cells
- Requires clinical trial that enrolls a diverse patient cohort that reflects disease incidence across demographics

Status: Abstracts complete, final proposals invited

NITRO aims to deliver:

Joints with the ability to heal themselves



PSI: Precision Surgical Interventions

Program Overview

Develop novel **precision detection and visualization tools** that let surgeons detect tumor margins and anatomical structures during surgery, ensuring surgeons remove all of the cancer the first time without inadvertent injury—preventing further surgeries and saving patient lives.

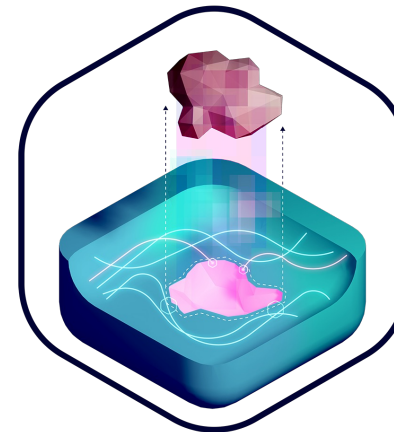
Technology focus areas

- Devices, dyes, and algorithms to assess tumor edges during surgery
- Devices, dyes, and algorithms to visualize critical anatomical structures during surgery

Status: Program Announced on July 27th

PSI aims to deliver:

"One and done" surgeries for cancers and other pathologies



Resilient, Extended, and Automated Cellular Therapies (REACT)



**Dr. Paul Sheehan,
Program Manager**

Vision: Develop a platform that enables patients to easily manage chronic diseases: an implanted Living Pharmacy, controlled by the patient, would automatically produce therapies long-term; an implanted Living Sentinel would inform the patient of the state of their disease

Technology focus areas:

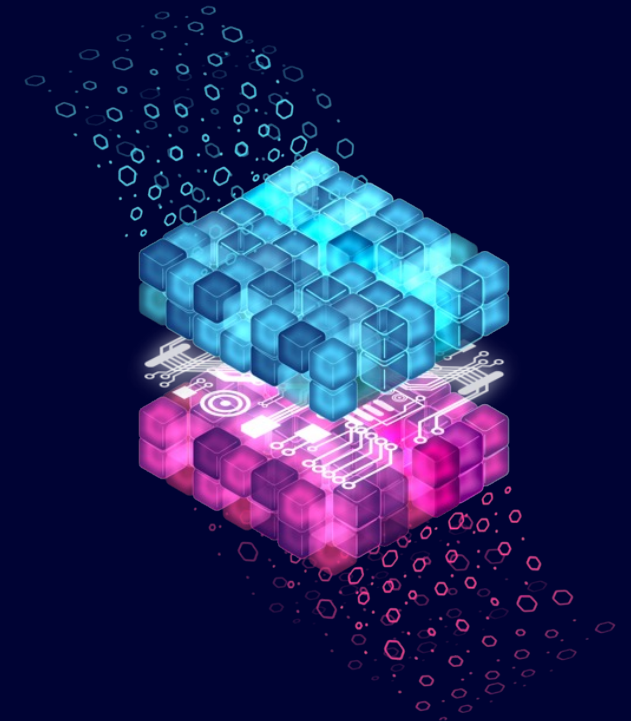
- Resilient cellular factories that produce therapy on demand from inside the body
- Bioelectronic devices to control the cellular factories
- Sentinel cells that track hormones or cytokines
- Improved encapsulation to protect the device from the immune system

Link to
REACT
webpage



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**What if your body could make its
own medicine?**



Antigens Predicted for Broad Viral Efficacy through Computational Experimentation (APECx)



**Dr. Andy Kilianski,
Program Manager**

Link to
APECx
webpage



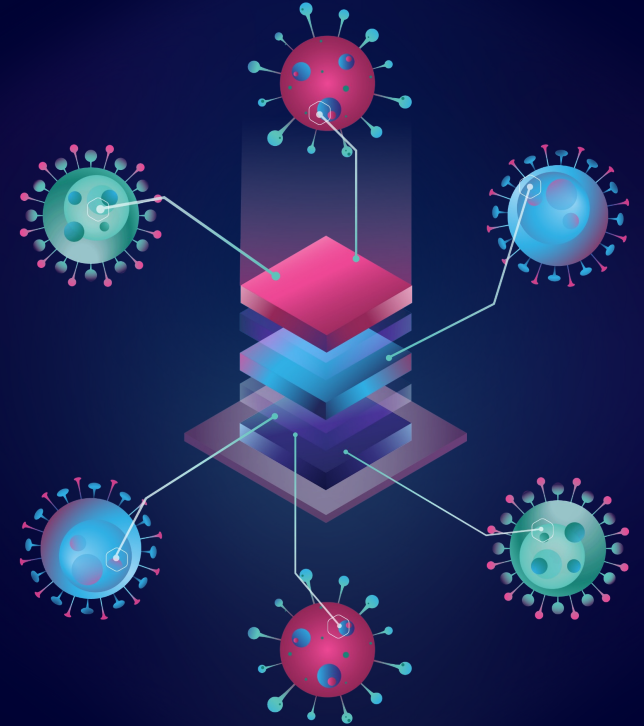
Vision: Develop the toolkit that makes broadly effective and evolution-resistant vaccines against viral pathogens possible for all.

Approach: Harness cutting-edge computational methods alongside unprecedented scales of biochemical and immunological data.

Why ARPA-H? Create a fast-track vaccine development pipeline that'll neutralize whole classes of viruses using groundbreaking tools not yet to be applied in vaccine R&D.

Technology Focus Areas

1. High-throughput biochemical analysis and protein function engineering
2. Antigen design and modeling pipelines for vaccine development
3. Proof-of-concept translational candidate development and clinical trials



**What if we could eliminate viruses as
current and future health threats?**

What if Vaccines Worked Against Multiple Viruses?

APECx Teams Targeting Genus-Level Efficacy - aiming to take virus threats off the table

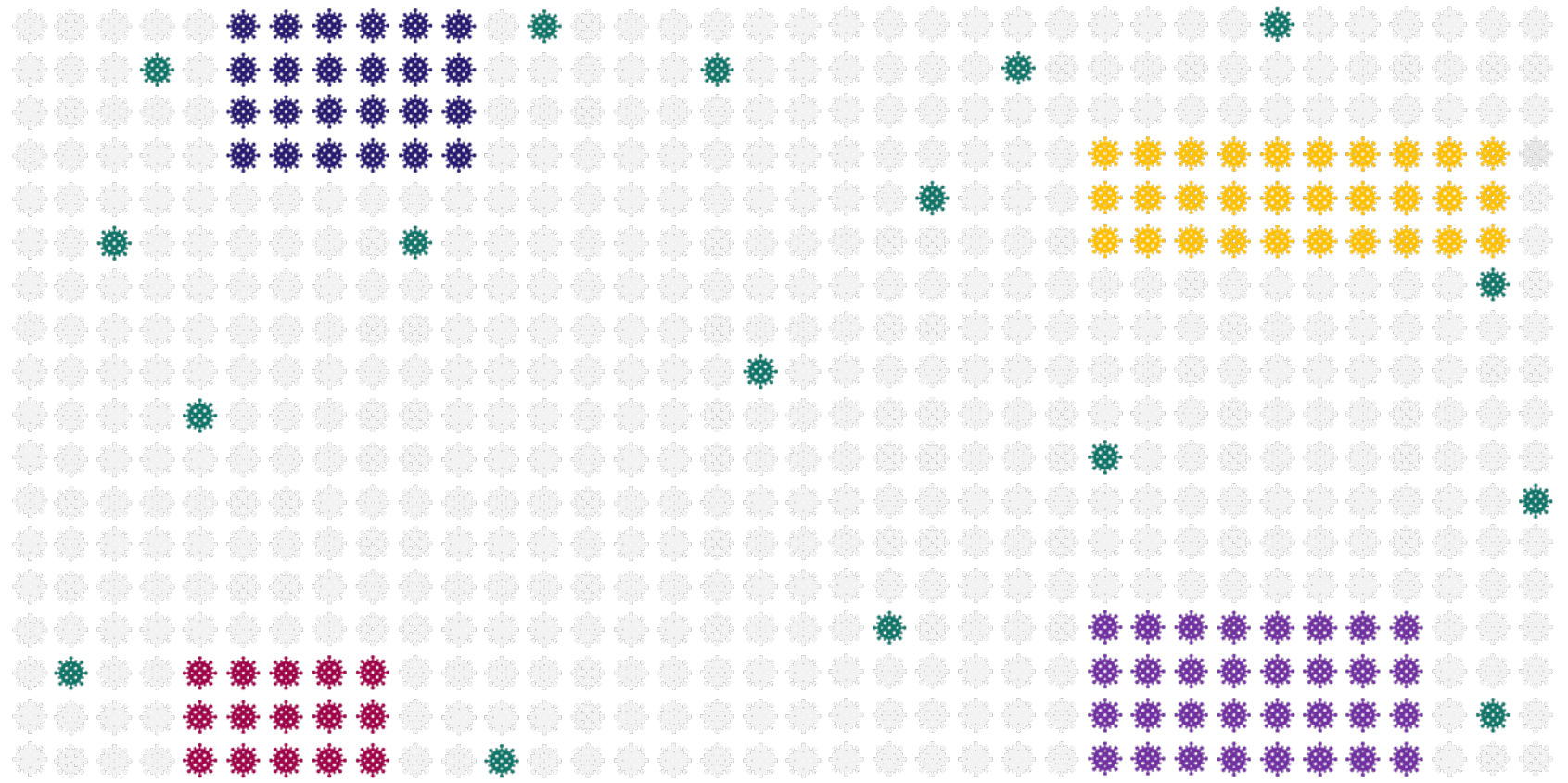
Genus #1

Genus #2

Genus #3

Genus #4

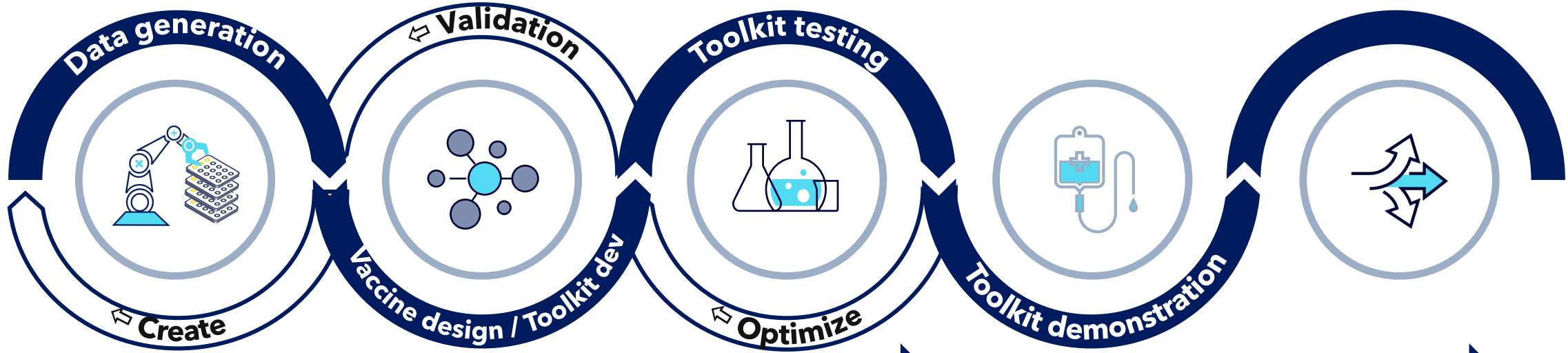
...while building the toolkit to target **all** viruses with computationally designed antigens



The APECx Approach

Toolkit Development and Proof-of-Concept

Technology Demonstration



Phase I (36mo)

Phase II (24mo)

HT Analysis (TA1)

Model Development (TA2)

Toolkit Evaluation (A separate TA2-only Team)

Translation (TA3)

Phase I Clinical

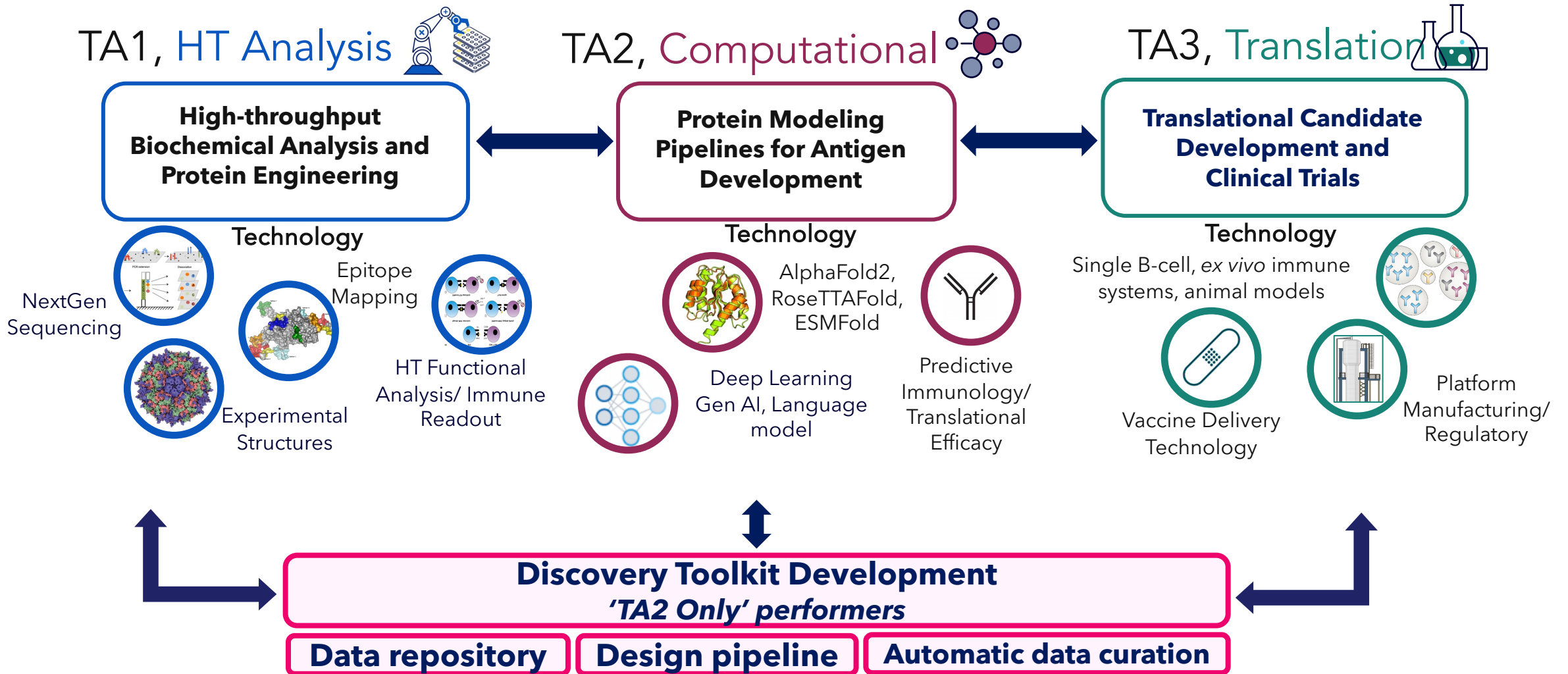
- Complete IND-enabling studies & Phase I Clinical Trials

Survive in the Wild

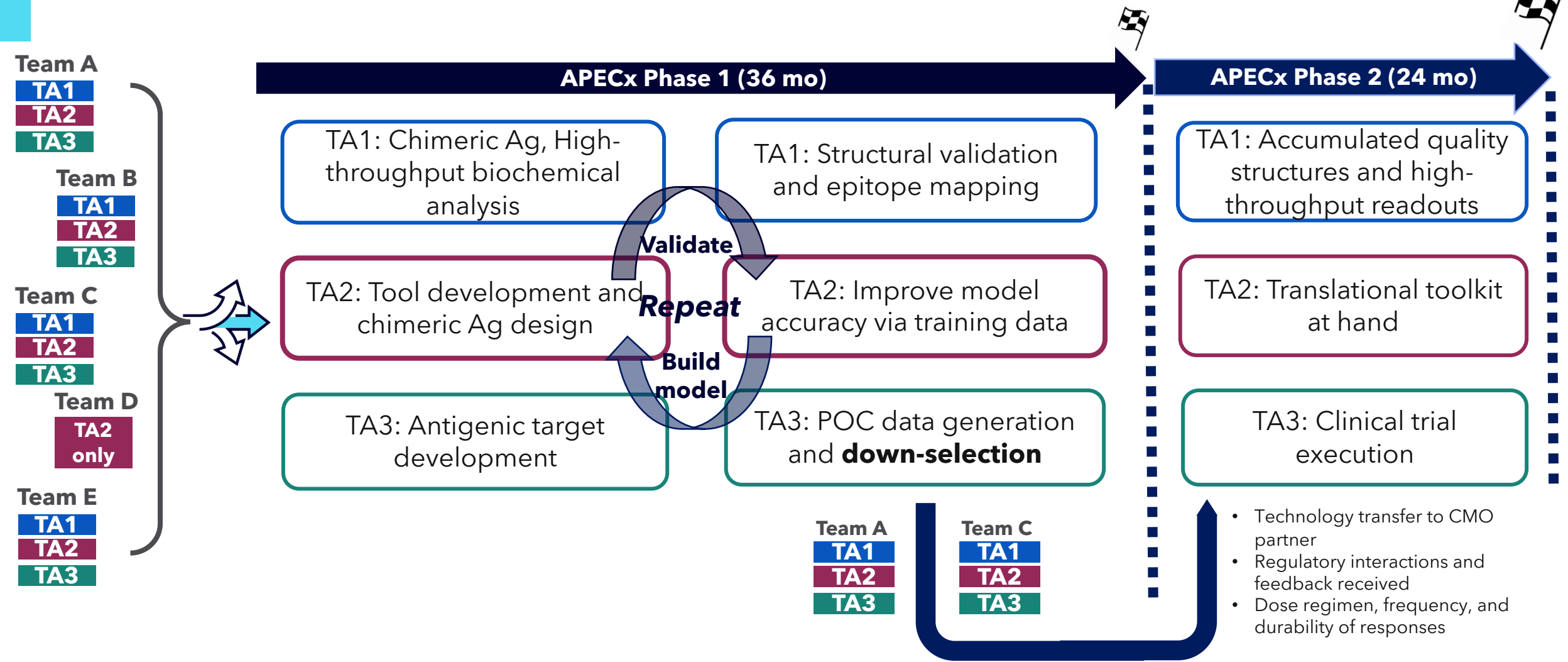
- Phase II Clinical Trials
- Accelerated approval pathway identified

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APECx Program Structure



APECx Execution

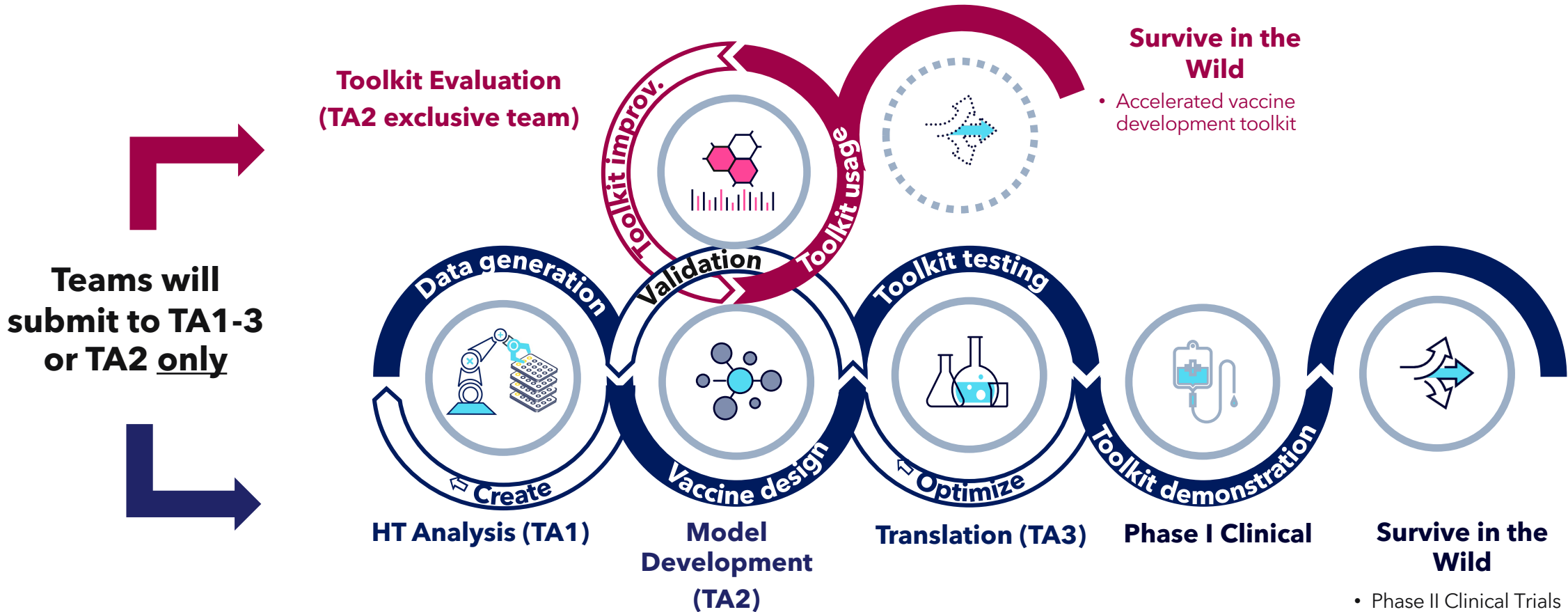


Submission Timelines and Feedback

Important Dates to Remember



APECx Execution



Impact of APECx:

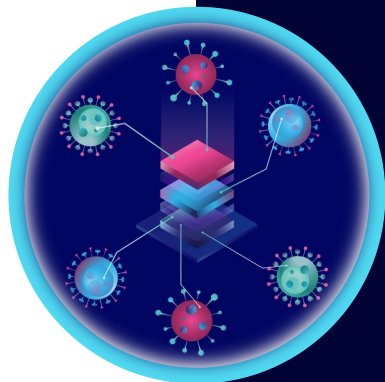
Viral burdens of today...

Over 270 viruses infect humans:

- Less than 10% of human viruses have vaccines regularly used in the U.S.
- The few broadly-effective vaccines that are available are inadequate.

Current Vaccine Development Workflow:

- Vaccine development relies on previous experimental data to inform target selection and is not always accurate.
- The average vaccine development time is > 10 years, costing ~ \$1B USD.



To a future without viral disease burden

Protection from all known and unknown viruses:

- Long-lasting **genus-level** vaccines for multiple viral diseases (cancer, autoimmune diseases, neurological diseases, acute disease, and chronic illness).
- Decrease in the **disease burden** experienced by patients, healthcare providers, and the overall economy.

Accelerated by AI/ML-aided Biologics Design:

- A **toolkit**/pipeline for on-demand MCM design.
- Manufacturability and efficacy built-in from the design stage.
- Reduced time and cost for development.