PATCH FORWARD PRIZE

Concept stage information session

April 18, 2024

This session is being recorded.
The recording will be published on **PatchForwardPrize.com**

Agenda

- Introduction and opening remarks
- Overview
- Competition structure
- Concept Stage details
- How to submit
- Q&A

Introductions

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PATCH FORWARD PRIZE

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Overview

PATCH FORWARD PRIZE

The Patch Forward Prize is a **$50 million Project NextGen competition** to advance microneedle patch-based RNA vaccines.

BARDA calls on **vaccine developers** and **patch makers** to partner and accelerate new vaccine technologies.

The need for vaccine innovation

The modern syringe has been the dominant vaccine administration method for 170 years. However…

- **Fear of needles** contributes to vaccine hesitancy.
- Prefilled syringes and vials require complex cold chain storage and transport, which can **limit access to vaccines**.
- Intramuscular vaccines need to be administered by **trained healthcare providers**.
- Intramuscular injection may be a **less efficient method** for eliciting protective and durable immunity.

The opportunity

Patch-based vaccines could address many of these limitations, and may elicit strong immune responses and durable protection.

- Developing compatible patch-based RNA vaccines presents technical challenges.
- Bringing these products to market will require partnerships between vaccine developers and patch makers.

The Patch Forward Prize will foster industry collaboration and support the advancement of patch-based RNA vaccine candidates toward the completion of Phase I clinical trials.

How will the Patch Forward Prize work

Prize competitions **complement** more traditional government funding mechanisms (e.g., grants and contracts) to **catalyze breakthrough innovation**.

The Patch Forward Prize:

- Encourages a variety of solution types and collaborations.
- Will evaluate how well submissions meet Concept, Preclinical and Clinical Stage evaluation criteria.
- Will award flexible, non-dilutive funds and non-monetary resources to support acceleration.

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Competition structure

Competition awards

$50 million total prize pool

Concept Stage
$8 million

Up to four Concept Stage winners will each receive a $2 million Concept Stage award.

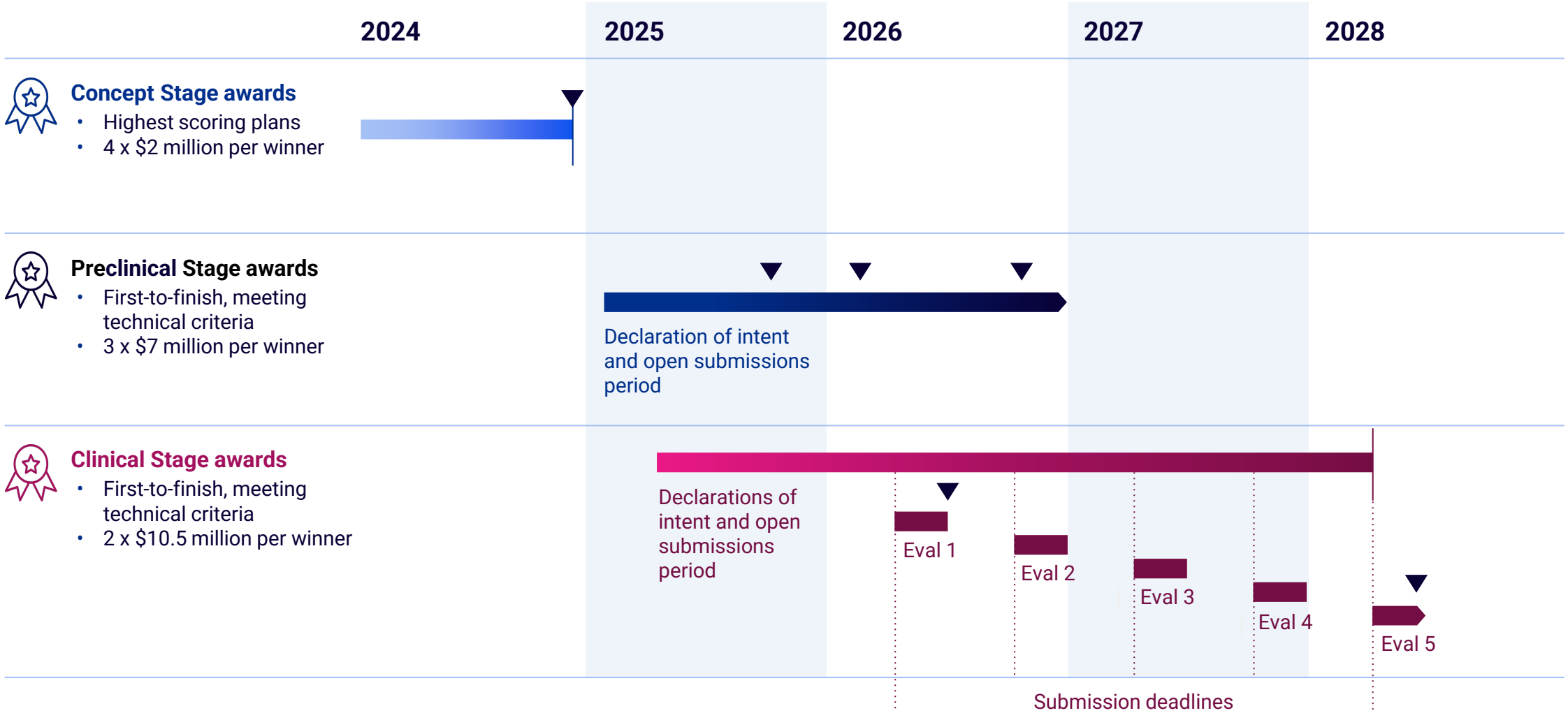
Preclinical Stage
$21 million

Up to three Preclinical Stage winners will each receive a $7 million Preclinical Stage award.

Clinical Stage
$21 million

Up to two Clinical Stage winners will each receive a $10.5 million Clinical Stage award.

Competition stages



Concept Stage

Development plans

- This stage calls on all eligible entrants — namely RNA vaccine developers and patch makers engaging in strategic partnerships — to submit **concept papers**.
- Concept papers must include plans for developing a patch-based RNA vaccine in **COVID-19**, **seasonal and pandemic influenza**.
- Submissions will be accepted between **August 1** to **October 3, 2024**, and will be evaluated during the Concept Stage review period.
- A panel of judges, composed of federal employees, will evaluate submissions based on the Concept Stage evaluation criteria.
- Judges will recommend up to four Concept Stage winners to each receive $2 million.

Preclinical Stage

Investigational New Drug (IND) application enabling studies

Declarations of intent

Prospective entrants must declare their intent to compete in the prize by providing their preclinical study plans to the Patch Forward Prize. Based on review of this declaration, the prize will accept qualifying entrants into the Preclinical Stage.

Preclinical Stage technical papers

Once accepted, Preclinical Stage entrants will be able to submit technical papers detailing outcomes of preclinical activities required for clinical development of a patch-based RNA vaccine.

Final guidance will be published prior to Preclinical Stage launch.

Clinical Stage

Phase I clinical trials

Declarations of intent

Prospective entrants should be ready to submit an IND to use their product in a clinical protocol **that has not previously been filed with the FDA**. Prospective entrants must declare their intent to compete in the prize by providing their clinical study plans and entrant-defined target product profile. Based on review of this declaration, the prize will accept qualifying entrants into the Clinical Stage.

Clinical Stage technical papers

Once accepted, Clinical Stage entrants will be eligible to submit technical papers detailing outcomes of their Phase I clinical trial for a patch-based RNA vaccine.

Final guidance will be published prior to Clinical Stage launch.

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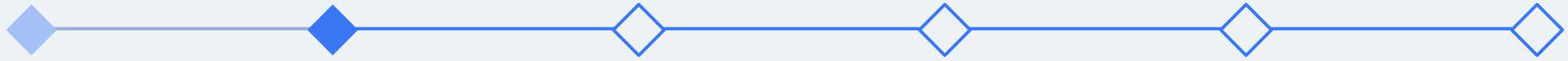
Concept Stage details

Concept Stage timeline



Concept Stage launch
March 28, 2024

Virtual information session
April 18, 2024

Concept Stage submissions open
August 1, 2024

Concept Stage submission deadline
October 3, 2024

Concept Stage evaluation
October-November 2024

Concept Stage winner announcement
November-December 2024

Concept Stage submission requirements

Concept papers should not exceed 10 pages, submitted as a PDF and formatted with 1-inch margins (2.5 cm), using an easily read font with minimum 12-point font size for prose and 10-point font size for tables and charts.

Criteria	Description
Concept summary	A summary of the development plans to demonstrate the proposed product can deliver COVID-19 or influenza RNA vaccines intradermally, and achieve safety, tolerability, immunogenicity, and product consistency.
Product description	A description of the proposed combined patch-based RNA vaccine product. Entrants should demonstrate the feasibility of the combination product, including any supporting evidence.
Past progress and current status	A summary of current development status and description of past progress, as well as any past funding and how it has been used to advance development to date. The summary should also include a description of any prior interactions with FDA regarding the proposed product.
Clinical and regulatory plan	A roadmap for engineering, formulating, and validating the proposed product through preclinical and Phase I studies. Roadmaps should include a detailed plan to obtain FDA regulatory authorization for an Investigational New Drug (IND) to be used in clinical trials, and an overview of the downstream clinical studies. Preclinical and clinical studies should enable appropriate statistical analyses of primary endpoints (e.g., functional immune assay(s)) and provide clear metrics for success.

Concept Stage submission requirements continued

Criteria	Description
Manufacturing plan	A roadmap to produce Good Manufacturing Practice (GMP) material, including any existing evidence for developing manufacturing parameters, processes, controls, and an approach to demonstrate manufacturing uniformity and consistency for clinical use in Phase I clinical studies.
Risk management	A summary risk register and an overview of the organizational or program-based mechanisms that will be used during the execution of product development to assess, monitor, mitigate, and manage risks.
Operational capabilities	A summary of the organization's expertise, including key personnel, access to required technology, and identification of any gaps in expertise and capabilities or additional partnerships required for product development.

Concept Stage evaluation criteria

Criteria	Description
Product design	The degree to which the submission provides a credible approach to combining an RNA vaccine and microarray patch into a product that delivers consistent intradermal doses under acceptable storage conditions for clinical use. The degree to which the submission demonstrates feasibility of the proposed combination product, including supporting evidence.
Clinical development	The degree to which the submission provides a realistic and sufficiently articulated plan toward completing Phase I clinical evaluation of a patch-based RNA vaccine combination product, including defining appropriate functional immune assays and associated success criteria, aligned with FDA requirements for an Investigational New Drug (IND) application.
Regulatory and risk-mitigation plan	The degree to which the submission provides an appropriate plan for effective engagement with the FDA, and to effectively compile evidence for a submission of an IND application. The degree to which the submission demonstrates an approach to assess and mitigate risks associated with product development.

Concept Stage evaluation criteria continued

Criteria	Description
Manufacturing	The extent to which the submission details plans for consistent manufacturing for clinical evaluation, including any preliminary manufacturing data that indicates Phase I clinical trial readiness.
Operational readiness	The extent to which the submission demonstrates the entrant has sufficient expertise and capabilities to usher the product through a Phase I clinical trial, including access to necessary intellectual property. The degree to which the submission identifies any additional capabilities that may be required and provides a clear approach to addressing those needs.

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How to submit to competition

Entrant profile

- The competition encourages partnerships, however **a single legal entity must serve as the entrant.**
- Each entrant must identify an individual to serve as the team lead and primary contact.
- **Only the entity that submits to the competition is eligible receive a Patch Forward Prize monetary award**.

Eligible entities

- The Patch Forward Prize is open to legal entities, both **domestic** and **international.** The entrant must not be prohibited from transactions with or import into the United States, as designated or sanctioned by the United States Treasury's Office of Foreign Assets Control, or include any entities or individuals designated or sanctioned as such in OFAC's List of Specially Designated Nationals and Blocked Persons.
- Entrants must demonstrate that they will have access to the required intellectual property for both the RNA vaccine and patch technology platforms, or a documented pathway to acquire that access.

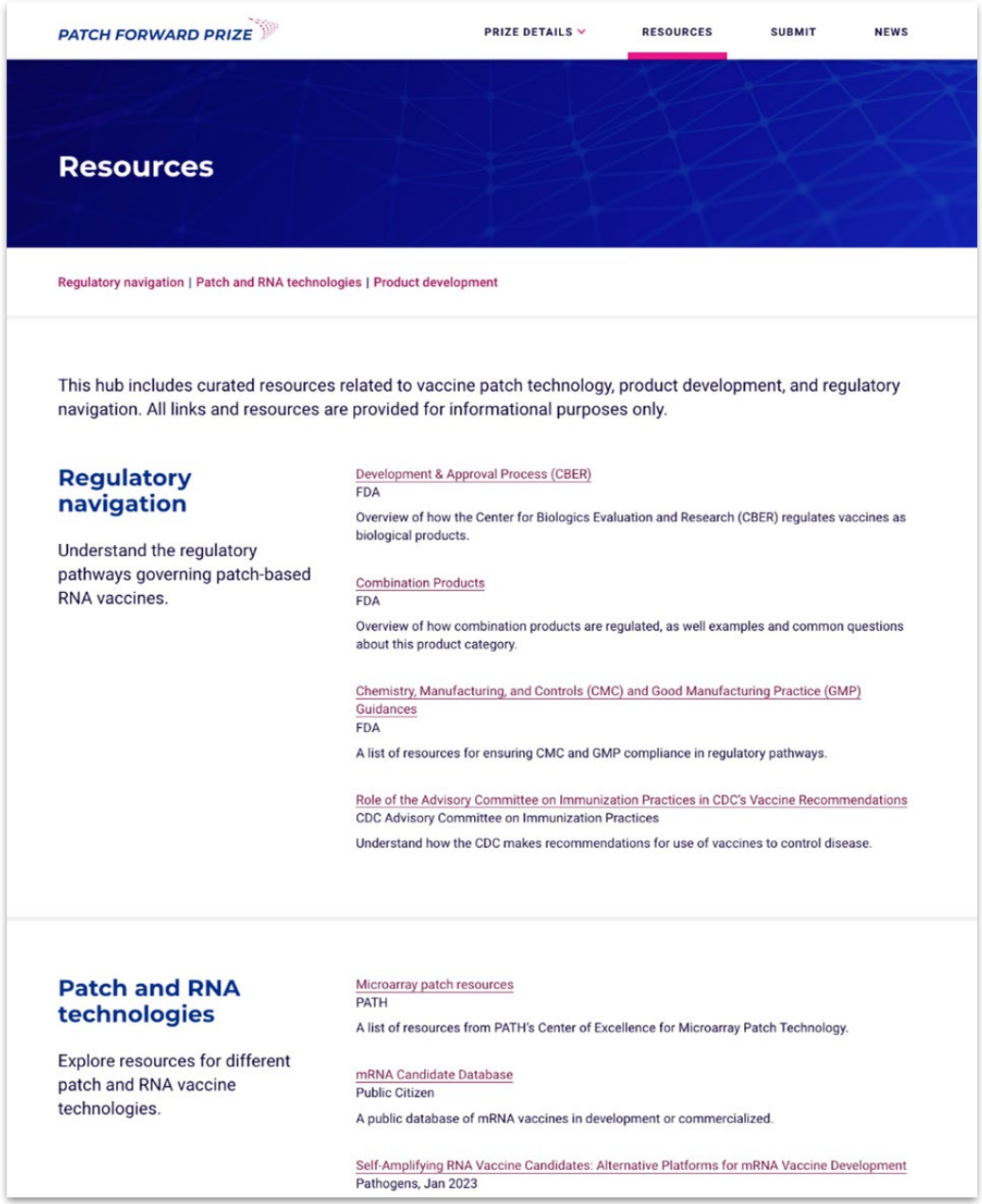
***Summary only**. Please **closely** review* **PatchForwardPrize.com** *for full registration and submission requirements, and additional guidelines.*

How to submit

- Entrants should closely read all details on the competition website: **PatchForwardPrize.com**.
- Entrants must comply with all requirements and accept and abide by all competition rules, terms, and conditions detailed at **PatchForwardPrize.com**.
- An authorized representative should register for the prize on the competition platform which will open on **August 1, 2024 at 9:00 a.m. ET**.
- Entrants should complete the online submission form, upload their concept paper, and affirm eligibility and compliance no later than **October 3, 2024 at 4:59 p.m. EST**.

Resources

- **PatchForwardPrize.com** includes curated resources related to vaccine patch technology, product development, and regulatory navigation.
- All links and resources are provided for informational purposes only.
- If you're interested in teaming and partnerships let us know via **hello@PatchForwardPrize.com**.

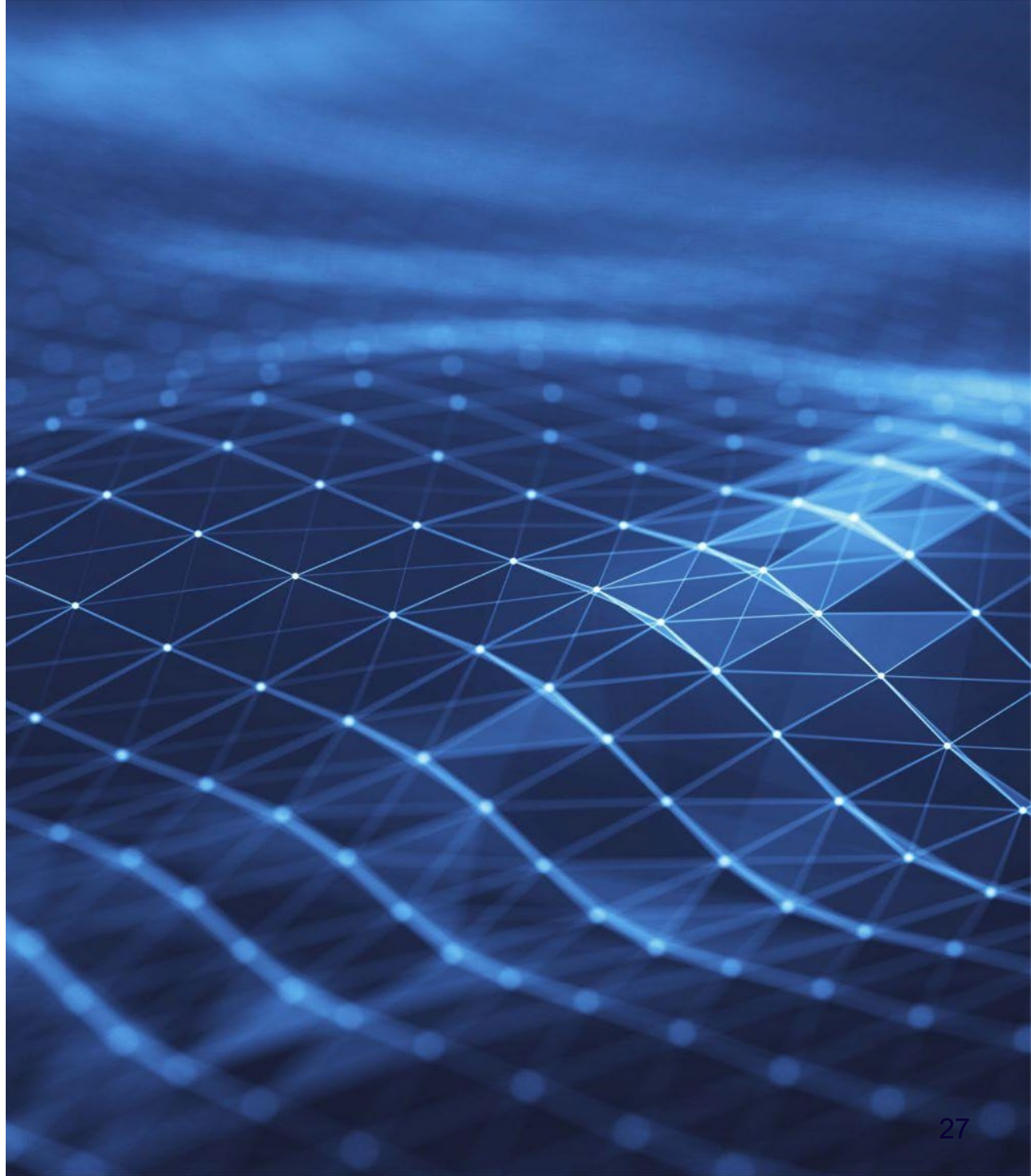


Stay up to date

Sign up for the challenge newsletter.

Visit **PatchForwardPrize.com** for:

- Complete challenge details
- Rules, terms, and conditions
- Curated resources
- Submission platform
- News and updates



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Questions

Sign up to receive the
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Thank you!

Contact:

hello@PatchForwardPrize.com