Patch Forward Prize Virtual Information Session

Transcript

PATCH FORWARD PRIZE

Carthur Wan, Luminary Labs [00:00:30]:

Okay, I think we will kick off now. Welcome, everybody, to the Patch Forward Prize virtual information session. Thank you all for joining us today. We are excited to tell you more about this prize competition. A couple of quick housekeeping notes, this session is being recorded, and the recording and slides will be posted on the competition website. Now, for today's agenda.

[00:01:30]:

In terms of what we will be covering during the virtual information session, we will begin with some brief introductions. And after some opening remarks, we will provide some context on the prize and an overview of the prize as a whole, followed by details on the current Concept Stage and how to submit for this stage of the Patch Forward Prize. We will conduct a Q&A at the end of the session, and if you have questions throughout the session, please submit them using the Q&A feature down at the bottom of the Zoom webinar window. We will endeavor to answer questions as we can during the session, but those that we are not able to provide immediate answers during the Q&A, we'll take on notice, and may be able to provide answers subsequent to this information session. We will publish a summary of questions received and responses in a frequently asked questions section, along with the webinar recording on the competition website. Now for some introductions.

[00:02:00]:

My name is Carthur Wan. I'm an Engagement Manager at Luminary Labs. We are a strategy and innovation consultancy based in New York City, and we are working with BARDA on the design and execution of this competition. I'm joined by some of my colleagues who are also working with BARDA on this competition, and will be presenting alongside Bella Li.

Also joining us today and representing the Biomedical Advanced Research and Development Authority, also known as BARDA, I'd like to now invite Dr. Robert Johnson, the Director of the Medical Countermeasures Program, to provide us with some opening remarks.

Robert Johnson, BARDA [00:02:30]:

Great. Thank you so much. And welcome, everyone. We're so glad you were able to join us to learn more about the Patch Forward Prize which BARDA launched last month. BARDA's mission is to develop medical countermeasures that address the public health and medical consequences of chemical, biological, radiological, and nuclear accidents; incidents and attacks; pandemic influenza; and emerging infectious diseases. Within BARDA, DRIVe's mission is identifying and de-risking the world's most promising technologies and capability no matter their origin, for the development of tomorrow's medical countermeasure.

[00:03:00]:

As Director of BARDA's Medical Countermeasures Program, I oversee our portfolio of medical countermeasures that are being developed to protect against public health emergencies, including pandemics. As part of this effort, we are always looking for approaches to find new partners and support new technologies, which leads me to the main theme for this seminar and learning session that you're at today.

[00:03:30]:

The $50 million Patch Forward Prize is among the largest incentive prizes in the history of the federal government. With it, BARDA and Project NextGen are demonstrating that open innovation can be used to stimulate product and technology development that is vital to public health. The prize is part of the U.S. government's larger $5 billion initiative, Project NextGen. Project NextGen's goal is to accelerate and streamline the rapid development of the next generation of vaccines and treatments through public/private collaborations.

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So why is BARDA conducting this prize? We're currently in a pivotal moment, when we have an opportunity to enhance our nation's preparedness against future pandemics. The Patch Forward Prize is a response to this need, aiming to drive innovation in vaccine delivery technologies. By putting our efforts towards vaccine innovation, particularly how vaccines are administered, we could help address a number of limitations associated with existing vaccines and immunization programs. For the Patch Forward Prize, we are calling on vaccine developers and patch makers to form strategic partnerships to accelerate new vaccine technologies. This is a unique funding mechanism to foster industry collaboration and support the advancement of patch-based vaccine candidates.

[00:05:30]:

Why patches? Innovation in the field of RNA vaccines and alternative routes of administration can provide individuals with optionality and address existing limitations. Microneedle patches have potential to reshape how vaccines are administered and our approach to public health emergency responses. The COVID-19 pandemic highlighted a number of limitations in how vaccines are currently administered. Scientists estimate the risk of another COVID-like pandemic is increasing, therefore it's a significant likelihood we'll experience another pandemic in our lifetime. We want to be ready for it. But when we think about it, patch-based vaccines have tremendous potential to simplify the process of formulation, storage, transport, and administration. In other words, attributes that can have an impact far beyond responding to public health emergencies. We hope to see many of you submit concept papers on October 3rd. Thank you for your interest and excitement about the prize. At this point, I'll turn it over to the prize team to share more. Thank you.

Carthur Wan, Luminary Labs [00:06:00]:

Thank you very much, Dr. Johnson. So, as Dr. Johnson mentioned, the Patch Forward Prize is part of Project NextGen. It is a $50 million competition to advance microneedle patch-based RNA vaccines. But why do we need innovation in this space? The way that we administer vaccines has remained largely the same for 170 years. It has served us well, but the lack of approved options available to administer vaccines does present challenges. Fear of needles is part of what drives vaccine hesitancy. And the use of prefilled syringes and vials requires complicated cold chain logistics. Intramuscular injections also need to be performed by trained healthcare professionals. All of this can serve as a barrier to vaccine accessibility and uptake.

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Adding to all of this, muscle is not as readily enriched with immune cells to elicit protective and durable immunity. Patch-based vaccines present an opportunity. The technology could address many other limitations and better prepare us for the risk of future pandemics, as Dr. Johnson mentioned. Fear of needles becomes a non-issue. And patches may reduce the need for cold chain transport and storage, and even have the potential for self-administration.

[00:08:00]:

Delivery of vaccine into the layers of the skin may also produce strong immune responses and durable protection more efficiently. But there has not yet been an FDA-approved and marketed patch-based vaccine. And making patch-based vaccination compatible with RNA vaccines, which is also a promising technology for vaccination, presents technical challenges. Developing products that combine patch technology and RNA vaccines will require strategic partnerships. The Patch Forward Prize is designed to address these challenges by fostering industry collaboration and supporting the advancement of patch-based RNA vaccine candidates towards completion of Phase I clinical trials.

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Now, it is important to note that the Patch Forward Prize is a prize competition. It works a bit differently from some of the other programs that BARDA runs and people may be familiar with, which may award funds through grants and contracts. Prizes aim to complement those types of government funding. As such, the Patch Forward Prize does not prescribe a specific solution type. It encourages a variety of solutions and collaborations, as long as they seek to meet the competition goals at each stage. Prizes award funding based on evaluation of submissions against predefined evaluation criteria. Rather than providing funds to undertake activity, they reward successful achievement of goals. And prize funds offer obligation-free non-dilutive funding.

[00:09:00]:

I'll now hand over to Bella, who will walk us through the competition structure and Concept Stage details.

Bella Li, Luminary Labs [00:09:30]:

Thanks, Carthur. So, to quickly introduce myself, my name is Bella Li, and I'm a Senior Associate at Luminary Labs. My team is leading the execution of this prize. And with the context provided by my colleague and Dr. Johnson in mind, let's delve into the competition itself. A quick reminder here is to please submit any questions via the Q&A function on Zoom, and we will be answering questions towards the end of the webinar.

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So the competition has a total prize pool of $50 million, dispersed across three different stages of the prize. The Concept Stage will award up to four winners; each winner will receive $2 million in awards. The Preclinical Stage will award up to three winners, where each winner will receive $7 million in awards. And lastly, the Clinical Stage will award up to two winners, where each winner will receive $10.5 million in awards.

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I'd also like to go over the timeline of the stages of the competition. We are currently in the Concept Stage. The judging panel will recommend up to four highest scoring submissions that meet the Concept Stage evaluation criteria at the end of this year. Both Preclinical and Clinical Stages will launch early next year in 2025, and commence in a first-to-finish approach. In the Preclinical Stage, the judging panel will recommend the first three submissions that meet the Preclinical Stage evaluation criteria. In the Clinical Stage, the judging panel will recommend the first two submissions that meet the Clinical Stage evaluation criteria. The specific timelines of both Preclinical and Clinical Stages will be announced and published later this year. So make sure you sign up for the competition newsletter to receive updates on these stages at patchforwardprize.com.

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The Concept Stage calls on all eligible entrants to submit concept papers detailing their technologies, proposed patch-based vaccine product, plans for development and plans for functional testing. The proposed product must include at least one of the following indications: COVID-19, trivalent or quadrivalent seasonal influenza, or pandemic influenza, the avian influenza A(H5N1). The vaccine products must also target or may also target any other indications concurrently, as long as it includes at least one of the three required indications. The concept papers are expected to address key considerations for product development and formulation, regulatory review and approval, preclinical and clinical evaluation, and

manufacturing processes to advance a safe, tolerable, and immunogenic patch-based RNA vaccine.

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Submissions will open on August 1st, and close on October 3rd this year. The judging panel, composed of federal employees, will evaluate the submissions based on the Concept Stage evaluation criteria during the evaluation period. And again, after this period, the judging panel will recommend up to four Concept Stage winners to each receive $2 million in awards.

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The Preclinical Stage asks eligible entrants to provide outcomes of preclinical activities that enable an IND application. To be eligible to enter this stage of the competition, entrants are not required to compete in the Concept Stage. But again, the proposed product must include at least one of the three indications: COVID-19, seasonal influenza, and pandemic influenza. Also, prospective entrants must declare their intent to compete in this stage by providing their preclinical study plans to the Patch Forward Prize. Based on the review of this declaration, the prize will accept qualifying entrants into the stage.

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Once accepted, the entrants will be able to submit technical papers detailing outcomes of preclinical activities required for clinical development of the proposed product. And this includes data package, containing the completed preclinical study results, evidence of meeting the success criteria of entrant-defined functional immune assays, a detailed outline of regulatory engagement activities, including pre-IND meetings and evidence of favorable FDA responses to any preclinical activities, and of course, the clinical study plans. This information can be found on the prize website at patchforwardprize.com, and more details on the Preclinical Stage declaration of intent process and the technical papers requirement will be published prior to the stage launch.

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The Clinical Stage asks eligible entrants who are planning to submit but have not yet filed an IND with the FDA to conduct Phase I clinical trials for a patch-based vaccine product. Entrants are not required to compete in the Concept Stage, nor the Preclinical Stage, to be eligible to enter this stage of the competition. Again, indication requirements stay the same. And similarly to the Preclinical Stage, prospective entrants of this stage must declare their intent to compete in the prize by providing their Phase I clinical study plans and an entrant-defined target product profile to the prize. Based on review of this declaration, the prize will accept qualifying entrants into the Clinical Stage. Upon acceptance, entrants will be eligible to submit technical papers detailing outcomes of their Phase I clinical trial, evidence of meeting the success criteria of entrant-defined functional immune assays, evidence of progress made by the vaccine product to

meet the entrant-defined target product profile. This information can also be found on the prize website, and more details on the Clinical Stage declaration of intent process and the technical papers requirement will be published prior to the Clinical Stage launch.

[00:18:00]

Now, let's dive deeper into the Concept Stage details. So we're here today at the virtual information session. The Concept Stage submissions will open on August 1st at 9:00 AM ET, and will close on October 3rd at 4:59 PM ET. The Concept Stage evaluation period will begin shortly after submissions close. Winners will be announced by the end of December. The concept paper should be a no more than 10-page document that addresses seven key topics.

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First, concept summary. So this should be a summary of the development plans to demonstrate the proposed product can deliver RNA vaccines intradermally. Product description, which is a description of the patch-based RNA vaccine product. Entrants should demonstrate the feasibility of the proposed product with any supporting evidence here. Past progress and current status, which is 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. This summary should also include a description of any prior interactions with the FDA regarding the proposed product. Clinical and regulatory plan, which entails a roadmap for engineering, formulating, and validating the proposed product through preclinical and Phase I clinical studies. Please also include how you plan to engage with the FDA to obtain an IND approval.

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Manufacturing plan. Entrants should provide a roadmap to produce GMP materials for developing manufacturing parameters, processes, controls, and an approach to demonstrate manufacturing uniformity and consistency for clinical use. Risk management. This entails the provision of a summary risk register and an overview of the organizational or program-based mechanisms that will be used during product development to assess, monitor, mitigate, and manage risks. Lastly, the concept paper should address operational capabilities by providing 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. Please note that this is a summary so make sure you carefully read all information presented on the competition website about what we're looking for in concept papers and the requirements for submission. You can access the detailed information by clicking the submit button at the upper-top right corner of the competition website.

Now, let's go over the evaluation criteria. Five equally-weighted criteria will be used to evaluate submissions. I'll share the definitions here. And these are also posted on the competition website if you'd like to read along.

[00:23:30]:

First criteria, product design. We're looking at 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. Clinical development. The degree to which the submission provides a realistic plan toward completing a Phase I clinical study of the patch-based vaccine product. 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 judging panel will also evaluate how the submission addresses risks. Manufacturing. The extent to which the submission details plans for consistent manufacturing, including any preliminary manufacturing data that indicates Phase I clinical trial readiness. And lastly, 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.

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Now that we've shared the structure of the Patch Forward Prize, let's talk about how to enter and how to submit to the competition. So the competition encourages partnerships, however, a single legal entity must serve as the entrant. Each entrant must identify an individual to serve as a team lead and primary contact. Only the entity that submits to the competition is eligible to receive a monetary award. In addition, the Patch Forward Prize is open to both domestic and international entities. The entrant, however, must not be a legal entity that is prohibited from transactions with or import into the United States, as designated or sanctioned by the United States. Again, entrants must demonstrate that they will have access to the required intellectual property for both the RNA vaccine and patch technology platforms, or provide a documented pathway to acquire that access.

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On the submission page of the competition website, you'll be able to view the submission requirements and detailed instructions for submission in its entirety. You can register for the competition once Concept Stage submissions open on August 1st. You should review all rules, terms, and conditions in-depth and ensure compliance with the competition requirements before submitting. Once you're ready to submit, you should complete the online submission form, upload the concept paper, and go through your submission again to affirm eligibility and compliance. Once submissions close on October 3rd, you will not be able to access the submission form. In addition, there are resources offered to potential entrants listed on the website under the Resources page. The curated resources are related to RNA vaccine and patch technology, product development, and regulatory navigation. If you are also interested in teaming and partnership, please contact the prize at hello@patchforwardprize.com. We will also be sharing news about the prize, especially details of later competition stages via our newsletter. So again, please sign up for the newsletter to stay on top of the competition details.

[00:27:30]:

We have now reached the Q&A portion of today's session. Thank you to those who have already submitted questions to the prize team. A reminder to please input your questions in the Q&A function and we'll get to as many of your questions as we can in the time remaining, and we'll also post answers to those and other frequently asked questions on the competition website soon.

Carthur Wan, Luminary Labs [00:27:55]:

So let's begin with some of the questions that we have received already.

We have been asked, "Can an entrant submit more than one concept paper?" Yes, entrants can submit more than one concept paper, as long as each concept paper describes a unique combination product. Related to this question, we have also been asked, "If an entrant submits more than one concept paper, how different do they have to be?" So each concept paper must describe a unique combination product in terms of the RNA vaccine technology or the microneedle patch technology, or both.

Bella Li, Luminary Labs [00:28:30]:

I have a question here, "Does the entity that enters the prize need to be a vaccine developer or do they need to be a patch maker?" So entrants must be a single legal entity and must meet all other eligibility requirements. There is no requirement that the entity has to be a specific type of company. However, entrants must demonstrate that they will have access to the required intellectual property for both the RNA vaccine and patch technology platform, or to provide a documented pathway to acquire that access.

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"Does an entrant need to have ownership of both RNA vaccine and microneedle patch technologies?" Again, no, but entrants must demonstrate access to the required IP.

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Another question, "Do partnerships need to be formed between RNA vaccine and patch companies before entering the Concept Stage?" The prize does not prescribe the type of legal relationships between companies with different technologies. However, to enter, the entrant must be a single entity. And again, only the entering entity will be awarded the monetary prize awards.

Carthur Wan, Luminary Labs [00:30:30]:

So, we do have a question here around whether the prize team will be connecting individual RNA vaccine developers and individual patch makers. The prize aims to create the environment to foster collaboration in an equitable manner. The prize team itself will not be doing individual match making between companies. Prospective entrants should review the available resources, as Bella mentioned, at patchforwardprize.com. And this does include resources that list patch makers and RNA vaccine developers at the time of publication. And we would advise you to sign up to the newsletter as we will publicize any potential opportunities for teaming and partnerships through the newsletter.

[00:31:30]:

We have a question on whether an entrant needs to be based in the US or include partnerships with entities based in the US. No, the Patch Forward Prize is open to all eligible entrants, both domestic and international, provided you meet all other eligibility requirements. Similarly to this question, "Are there regional restrictions on who can enter the prize?" No, there are no regional restrictions, but entrants to the prize cannot be an entity that is prohibited from transactions with or import into the United States, as mentioned earlier. And the Patch Forward Prize will comply with all current federal US laws and regulations as applicable.

[00:32:00]:

"Do entrants need to have some kind of academic affiliation in order to be considered for the prize?" The prize competition is not open to individuals, but it is open to any legal entity that meets all other eligibility requirements. So there's no requirement of an academic affiliation, but individuals are not eligible to enter themselves.

Bella Li, Luminary Labs [00:32:30]:

I have a question here, "What does the Patch Forward Prize define as a patch?" So for the purposes of the prize, a patch is a vaccine delivery system that can be applied to the body like a small adhesive disc or bandage, and consist of microscopic projections that penetrate the skin surface. The proposed product must be a single patch intended for intradermal RNA vaccine administration.

[00:33:00]:

Another question, "Is the prize seeking a specific type of microneedle patch?" So the Patch Forward Prize is agnostic toward the different types of microneedle patch technology.

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"Are DNA-based vaccines on patches in scope?" So, to emphasize, the Patch Forward Prize is a competition to advance microneedle patch-based RNA vaccines only.

[00:34:00]:

Another question, "What infectious disease targets are in scope for this call?" So, as mentioned earlier, the vaccine must target at least one of the three required indications of COVID-19, trivalent and quadrivalent seasonal flu, and pandemic flu, the avian influenza A(H5N1). However, the entrants may target any other indications as long as one of the required indications is included.

[00:34:30]:

A question on, "What product attributes will be considered when awarding Concept Stage prizes?" So judges will evaluate submissions based on the five official evaluation criteria that I walked through today. They're also published on the prize website. These criteria are equally-weighted. And then judges will score each submission based on the five criteria, and the entrants that have submitted the highest scoring submissions will be awarded the Concept Stage prizes.

[00:35:30]:

One question on, "Will the competition seek to diversify the awards across different types of microneedle patch?" So, no, the prize is, again, agnostic to the type of microneedle patch technology. Winners will be based on the judges evaluation and deliberation against the five official evaluation criteria I just mentioned.

[00:36:00]

And then one more question on, "What is the technology readiness level required for the Concept Stage?" So for the Concept Stage, we're asking for entrants to submit concept papers, and there's no expected current technology readiness level. However, the submissions should include an ambitious, but achievable development plan that addresses the key considerations we mentioned in this webinar, for product development and formulation, regulatory review and approval, preclinical and clinical evaluation, and manufacturing processes.

Carthur Wan, Luminary Labs [00:36:30]:

So we've been asked, "Does data need to be submitted as part of the Concept Stage?" So submissions should include supporting evidence from development and testing efforts to date. Concept Stage submissions will be evaluated, again, against the evaluation criteria, as Bella

mentioned, and this does include the degree to which the submission demonstrates feasibility of the proposed combination product, including supporting evidence.

[00:37:00]:

"Can clinical development plans provided in the Concept Stage extend beyond Phase I clinical studies?" So provided submissions have a detailed approach to advancing the proposed combination product through completion of a Phase I clinical study that demonstrates safety, tolerability, and immunogenicity in humans, there's no restriction on providing plans for clinical development beyond Phase I studies.

[00:37:30]:

"Can clinical development plans provided in the Concept Stage be seeking an accelerated FDA approval?" Again, clinical plans should align with FDA expectations, and entrants should detail in their submissions how they have or will use preclinical feedback interactions with the FDA to effectively design and refine the development program.

[00:38:30]:

"Are there financial or technical reporting requirements for prizes awarded, like with grants?" No, the prize itself has no reporting requirements. Entrants may have other federal funding and are responsible for complying with all requirements and restrictions of all federal funding received. Entrants using federal funds from a grant or cooperative agreement outside the prize should coordinate with the awarding official at the federal awarding agency. And entrants must also comply with all applicable federal state and local laws, regulations, and policies.

[00:39:00]:

"Can the Concept Stage awards be used to fund any aspect of patch combination product development, or are there restrictions on the use of funding prior to the Preclinical Stage?" So the prize does not restrict the use of funds awarded. And, as a reminder, winners of the Concept Stage are not required to compete in the Preclinical Stage, and participating in the Concept Stage is not a requirement to compete in the Preclinical Stage.

"Does successfully being awarded funds through the Patch Forward Prize impact the FDA approval process?" The prize itself does not impact the FDA approval process.

Bella Li, Luminary Labs [00:39:30]:

I have a question here, "For the Concept Stage awards, when should the projects plan to start? How long after the October 2024 deadline will awards be given?" So the Concept Stage awards

are anticipated to be dispersed in December this year. However, we don't have any prescriptive decisions on when you would start your own projects.

Carthur Wan, Luminary Labs [00:40:00]:

"Are early-stage startups with no prior clinical vaccine development eligible?" There are no requirements that entrants to the Concept Stage have prior clinical vaccine development.

Bella Li, Luminary Labs [00:40:30]:

I have another question here, "Is the intent for winners of the Concept Stage to continue on to the Preclinical and Clinical Stage awards? Or will Concept Stage winners not be eligible for the other categories?" So both the Preclinical Stage and the Clinical Stage are open to all entrants, including Concept Stage winners, but you are not required to compete in the Concept Stage, nor the Preclinical Stage to enter the Clinical Stage, and you're also not required to compete in the Concept Stage to enter into the Preclinical Stage. So there are stand-alone stages.

Carthur Wan, Luminary Labs [00:41:30]:

We have a question here on whether there are technical specifications regarding thermostability for the technologies. So, as part of the evaluation, during the Concept Stage, submissions will be evaluated on the degree to which the submission provides a credible approach to combining RNA vaccine and microneedle patch technologies into a product that can deliver the vaccine consistently, intradermally, under acceptable storage conditions for clinical use.

[00:42:30]:

"What if we are not able to manufacture? Would partnering with another GMP RNA manufacturer be allowed?" The Patch Forward Prize is not restricting the number or types of partners that an entrant has, provided that they can demonstrate, as part of their submission, 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 their access. So there are no restrictions there on partnering.

Bella Li, Luminary Labs [00:43:00]:

I have a question here, "Will the prize money be delivered to the winning entrant as one lump sum?" So the prize awards at each stage will be made in a single payment. So yes, it will be one payment.

Carthur Wan, Luminary Labs [00:43:30]:

"Can one company partner with more than one company to submit multiple concept papers?" So, yes, as mentioned earlier, entrants are able to submit multiple distinct concept papers, provided that the products are different. And, as noted earlier, they must be different in the context that either the RNA vaccine technology or the microarray patch technology is different. Or both.

"How are concept phase evaluation criteria weighted?" As Bella noted earlier, each of the concept phase evaluation criteria are equally weighted.

[00:44:30]:

I believe that many of the questions that we have received now may have already been covered, but we will review questions received and aim to address as many of them as possible in the frequently asked questions to be published afterwards as well. So I think now we will aim to wrap up the question and answer portion of this presentation.

Bella Li, Luminary Labs [00:45:00]:

Yes. And I will just share our prize QR code with all the folks who are participating in our webinar today. So thank you again for joining us. Hope that this has been an informative webinar on the Patch Forward Prize. If you have further questions and any inquiries, please feel free to contact us at hello@patchforwardprize.com. And, yeah, thank you again, and hope you have a good rest of your day.