Lead Detect Prize

Virtual information session transcript

Carthur Wan:

Welcome, everybody, to the Lead Detect Prize Phase 1 virtual information session. Thank you all for joining us today. We're excited to tell you about the challenge in the field, and then field as many of your questions as we can before the hour is up. Before we begin, and as people trickle in, a few housekeeping notes. This session is being recorded, and the recording and slides will be posted on the challenge website. If you have questions throughout the session, please submit them using the Q&A feature found at the bottom of the Zoom webinar window, and we'll also have an opportunity to submit questions at the end of the presentation. We'll get to as many of your questions as we can, either live or through a written response, but may have to take some on notice and publish these along with the webinar recording. So let's start with some introductions. Firstly, I'd like to turn to the team here with us today from the CDC, beginning with Paul Allwood.

Paul Allwood:

Okay. Thank you. Good afternoon everybody. It's really a pleasure to be on this call. My name is Paul Allwood. I am the branch chief for Lead Poison Prevention and Surveillance at the CDC, and really happy to have all of you join, and I'm going to pass it over to my colleague, Jeff Jarrett, to introduce himself.

Jeff Jarrett:

Hello. My name is Jeff Jarrett. I'm a lead research chemist in the division of Laboratory Sciences in Organic Radiation and Toxicology branch. My division seeks to improve American's health by developing lab methods to diagnose disease testing for exposure to harmful chemicals, helping other labs with improving the quality of their tests, and responding to public health emergencies. In this current project, my branch is providing subject matter expertise about blood lead testing at the point of care. Improvements that can be made around the technical challenges in that, in the Lead Detect Prize, for blood lead testing can have a large public health impact for improving public health.

Paul Allwood:

I think, Art, can you please introduce yourself?

Arthur Chang:

Yes. Good afternoon. So my name is Arthur Chang. I'm the Chief Medical Officer of the Division of Environmental Health Science and Practice National Center for Environmental Health, where the Lead program sits. I'm an emergency medicine physician and medical toxicologist. I've taken care of many children with lead exposure and understand how important this project is. Thank you.

Carthur Wan:

Thanks, Paul, Jeff, and Art, and so, introductions to myself as well. I'm Carthur Wan, I'm a senior associate at Luminary Labs, and we are a strategy and innovation consultancy based in New York City. I'm joined by my colleagues today. On the call, Emily, Naomi, Cameron, and John, and together we are designing and administering this prize on behalf of CDC and in collaboration with NASA's Center of Excellence for Collaborative Innovation. In terms of what we'll cover today in the session, we aim to provide some background about the challenges in blood lead testing at the point of care, and why there is an opportunity for an open innovation challenge. I'll, then, hand it over to Cameron to walk us through the details of the challenge and how to enter before we open up to some Q&A.

So let's begin with the background behind the Lead Detect Prize. The Lead Detect Prize is a $1 million challenge to enhance testing for lead and children. The challenge seeks to accelerate the development of next generation point of care blood lead testing technology, but before we get into the details of the challenge, it's worth providing some context. Why do we need a new approach to testing very low levels of lead and blood? In children, there is no safe level of lead and blood. Even very low levels of lead exposure present a risk to physical and intellectual development. Lead inhibits the absorption of essential minerals, such as iron, zinc, and calcium that are needed for proper development, particularly of the brain and nervous system.

Common negative health impacts include attention related behavioral problems, decreased cognitive performance, and high rates of other problem behaviors, as well as slowed growth and hearing problems and other wide-ranging adverse health effects. The impacts of lead exposure in children are thought to be irreversible, and those living in communities experiencing disadvantage are most likely to be living in environments where they may be exposed to lead due to older housing stock and other systemic and environmental issues. The impacts of lead exposure are not always obvious, and may not be apparent until the damage is already done during early childhood development. This means that childhood blood lead screening is an essential preventative measure against lifelong harms.

It makes a point-of-care blood testing with a minimally invasive sampling approach and essential public health tool. The alternative to point-of-care testing is a venous blood draw, a more invasive procedure which can be distressing for children and parents. It is

also less equitable and accessible as it may require travel to specialized facilities, and it cannot give an immediate result as the samples must be sent to a centralized lab. The Centers for Medicaid and Medicare services mandate that children enrolled in Medicaid be tested at ages 12 months and 24 months, but children not enrolled in Medicaid, CDC recommends focused testing efforts on children living in higher risk environments. Despite these mandates and recommendations, it's estimated that a quarter of children enrolled in Medicaid will not receive a test by age three.

However, it has been shown that access to point of tests helps to increase rates of blood lead screening. There is currently only one FDA cleared point of care blood lead test, which has been grounded clear waiver. This clear waiver means it can be performed by non-laboratory trained personnel. While it's an important tool, it is the only point of care option that we have had for more than a decade. In 2021, what's known as the CDC blood lead reference value was reduced from five micrograms per deciliter of blood to 3.5 micrograms per deciliter. CDC provides this blood lead reference value to support clinical decision-making and environmental policy. When a point of care test returns a result above this value, medical or environmental follow-up activity may be recommended.

But this reference value is now close to the limit of detection of the current point of care test solutions that we have. The closer a measurement is to the limit of detection, the greater the uncertainty in the result, and as lead is ubiquitous, this also increases the risk and impact of small amounts of environmental lead contaminating samples and affecting the results. This means that it's more difficult for clinicians to determine the best course of action from a point of care test when it gives a blood lead test result that is close to the reference value, and this uncertainty may result in unnecessary followup activities that can create burdens for families. This changing landscape has created an urgent need for improving technology to detect very low levels of lead exposure at the point of care.

This need is well met by an open innovation challenge, like a price competition. Price competitions work in tandem with other more traditional funding to support innovative solutions to progress. While grants and contracts often prescribed the desired solution or development pathway, this can limit the breadth of opportunity. We believe that a wide range of ideas and technologies may be able to solve this problem, and this may include in [inaudible 00:08:36] some biosensors, nano materials, and microfluidics, and other more approaches that we may not be aware of. Prizes allow us to be open to this wide range of different solution types and to allow novel collaborations across traditional silos. Another way in which prizes are different is who they can be awarded to and what they reward.

Traditional mechanisms, such as grants and contracts, are often awarded to institutions and organizations. They provide funds in advance of executing specific predefined activities that are agreed upon at the outset, and must remain the same over the life of a grant or contract. Prizes, on the other hand, balance rewarding progress and promise, and can be awarded to a range of individuals, teams, or entities as long as they meet defined eligibility requirements and that they deliver outcomes against clearly defined criteria. Prizes can also accelerate longer-term development by providing winners with flexible funding and non-monetary support, like access to facilities, expertise, networks, or other technical assistance.

Given all of this, our goal in Phase 1 of this competition and beyond is to leverage advancements across these diverse scientific and engineering fields to try and solve the issues in point of care blood lead testing. The Lead Detect Prize seeks to foster and accelerate the development of new, point-of-care test solutions that are reliable, accessible and efficient. Ideally, these solutions will be able to enhance equity of access to testing across the country and potentially beyond by aiming to provide solutions that are compact, easy to use, and affordable. We ought to see a wide range of approaches and collaborations that meet the challenge criteria and advance our goal towards a new generation of point of care blood lead tests. I'll now hand over to Cameron to provide some more details about the challenge structure.

Cameron Fox:

Thanks, Carthur. Hi, everyone. My name is Cameron Fox, and I am also a senior associate here at Luminary Labs, and so now we'll jump into some of the details of the prize itself. So in this section we'll walk through the prizes structure and timeline, what you can expect for prizes, what we're looking for in submission requirements, how they'll be evaluated, and what the judging criteria will look like. Next slide. So starting with the challenge structure, the Lead Detect Prize will be divided into two phases. Phase 1, which we are in right now, is open to all eligible participants, and calls on researchers and innovators to submit concept papers and development plans for new point of care blood lead tests. Phase 2, which will take place from February to September of next year, will advance on what we do in Phase 1, and we'll be open exclusively to Phase 1 winners.

Now, today we're going to mostly focus on Phase 1 given that that's where we are and it's more pertinent. Next slide please. So looking at our Phase 1 timeline, submissions opened on November 14th, we're obviously now in the information session here on December 7th, and you will have until January 22nd of next year to submit. Once we've collected all the submissions and the deadline has passed, there'll be a few weeks in January and February where we will have our judges look at the submissions. We plan on announcing those winners in February, and then moving into Phase 2. Next slide. So

in terms of prizes that you can expect, the Lead Detect Prize will award up to $1 million over the two phases. In Phase 1, up to 5 winners, where she receive an equal share of $150,000 prize pool and the chance to exclusively advance to Phase 2.

In Phase 2, up to three winners will receive a share of the remaining $850,000. Next slide. Now, getting into what we're looking for in terms of submission requirements. Phase 1 entrants should submit concept papers describing their approach to detecting very low concentrations of lead from whole blood samples when operated by healthcare workers without specialized training. The concept paper should be a maximum of 10 pages, and include each of the categories that we list here. A brief overview for your concept summary, this should be an overview of your proposed test and how it advances point of care testing using capillary blood samples. Your solution description should go into your methodology, including any scientific rationale, expected performance, and how you plan on mitigating both pre and post analytical error.

Description of use will describe how your test is usable by untrained operators at the point of care. Past progress and current status should be a summary of any previous progress or work you've done in test development, including past funding and, if available in the initial data or interactions with the FDA. Your development plan should speak to how youth are thinking about prototyping, iterating, testing in clinical populations and moving through FDA clearance. You should also speak to your estimated budget, timeline, and how stakeholders will be inputted there. Lastly, for a team description, we want to understand what your team's areas of expertise are, and importantly, where do you anticipate gaps in that expertise, and what might partnership look like for future development? Before we move on, I really want to harp on this text at the bottom, that this is just a summary.

I would really encourage you to look at the full requirements at LeadDetectPrize.com, as there are a lot of technicalities around formatting, layout, and typeface that we want to make sure you're aware of. Next slide. Now, after you submit, your concept papers will be evaluated by these six buckets, and they will all be equally weighted. Next slide? So looking at these, the first three of the evaluation criteria. For analytical performance, we're looking for two things. First, your proposal's potential to accurately and reliably detect low blood lead levels at the point of care and the strength of the scientific rationale of why you're making those claims. Second, error mitigation. Lead is ubiquitous in the environment and, as the reference value moves lower, it becomes more important that these tests aren't contaminated at any step along the process.

And so, we want to understand how you will identify and mitigate sources of contamination and how you plan on reducing overall error as your solution is developed. Next is user-centered design. Zooming out from detection itself, concepts will be judged

on their understanding of user needs. How does it fit into existing clinical workflows? How will it be used in the field, and how will you engage stakeholders going forward to ensure their input is taken into account? Next slide. Now, going into our second three, accessibility. We really want to ensure that this is accessible by folks across socioeconomic status and shown appreciation for broad, equitable adoption. So take into account things like affordability, scalability, and any other factors that will ensure it's available to a broad swath of children, especially those who are currently underserved.

Your development plan, here we're looking for a clear understanding of what it will take to move your concept paper to a successful product, considering things such as prototyping, iteration, testing/validation, and evaluation in addition to realistic estimates of your budget, resourcing opportunities beyond the challenge, and a cognizance of potential risks within your plan. Lastly, team. We want to understand the makeup of it and, like we said, you should highlight your expertise and be very honest about where your gaps are and how you plan on addressing them. Next slide. Beyond these evaluation criteria, we've developed a set of target performance metrics, which you can think of as your solutions North Star. Important to note that, during Phase 1, these metrics should be considered guidance toward a potential future product.

And make sure to refer to those evaluation criteria for how it'll be evaluated, but these are really the things that you should think about as you build it out. On this page we're discussing operating parameters, so these are metrics that pertain to the test itself, while on the next slide we will talk about some of the development parameters. So looking at these in more detail, first is the limit of detection. We're really aiming for solutions that can reliably detect blood lead levels at or below 1.5 micrograms per deciliter. Measurement precision is considering not only how small of an amount you can detect, but is it replicable, and does it operate well at important medical decision points? So 3.5, 20, and 45 micrograms per liter are very important to clinicians, and we want to make sure that your test works at each of those.

Measurement accuracy. You should indicate the ability to achieve accuracy [inaudible 00:19:22] 2 micrograms per deciliter or 10% of the true value, whichever is greater, across the reportable range. Analysis time. It's really important to think about the actual setting and the fact that this is going to be used at the point of care, and so we want to aim for solutions that can provide results in about 5 minutes. In terms of how your results are reported, your solution should be capable of electronically displaying the information there and transferring that data to EHRs in commonly used formats. That could be HL7 or others. And lastly, sample collection. You're aiming for collecting less than 150 microliters, which is why we talk about capillary blood versus venous, and we want to make sure that it has to be a capillary blood draw.

Next slide. So beyond the test operating parameters, two other target performance metrics to consider that pertain to usability and access. First is ease of use. The test should be capable of meeting the requirements for a CLIA waiver, which will enable it to be used by untrained healthcare workers and I'd encourage you to closely review the guidelines linked there for more information on what's required of that, and lastly, cost. We want to know that you've factored in the cost of the solution, thinking about both the device itself and the cost per test so that we can enable equitable access. Next slide. In terms of Phase 1 judging, after Phase 1 closes, a multidisciplinary group of judges will evaluate eligible submissions according to the criteria that we ran through here. Depending on the number of submissions we receive, there may be an initial screening before it goes to the review panel.

After their judging is finished, they will recommend up to five winners to move on to Phase 2. Next slide. So before we move on to questions, one last section here on how to actually submit and what eligibility requirements look like. Next slide. In terms of eligibility, there are three different ways that you can submit. First, you can submit as an individual. Submit on your own behalf, as long as you meet eligibility requirements, and this includes both folks in the US and internationally, and in this case, the prize will come directly to you. For teams, this can be a group of two or more submitters that also enter on their own behalf. In this case, the team lead must meet all of the eligibility requirements, and the prize will be dispersed to the person indicated as being the lead. Lastly, you may submit as an entity.

In this case, it can be either a single entity where all team members work. It could be multiple entities or folks inside of one, plus individuals. Regardless of which of those permutations, the prize will be awarded to the entity that is signed as lead. Next slide. So in terms of how to submit, you can go to LeadDetectPrize.com, register yourself or your team, and as long as you comply with all the requirements and accept the challenge rules, terms, and conditions, complete everything that we've walked through, and submit by January 22nd, you should be great. Next slide. In terms of federal grantees, so if you plan on using federal grant awards for your project, there are a few caveats and conditions that you'll have to consider.

First, the awardee institution must be the entity that you register under. Second, the use of funds in this challenge must be consistent with the purpose, terms, and conditions of your grant or award, and lastly, if you are awarded the prize, it has to be treated as program income for the purpose of the original grant. Federal contractors cannot use federal grants from a contract to develop their submission or to fund efforts in support of this submission. Next slide? In terms of intellectual property, at a high level, participants retain intellectual ownership of their solution; however, by entering you do grant CDC

non-exclusive license to reproduce, publish, post, link to share, create derivative works or display publicly the submission on the web or elsewhere throughout the world.

Again, please read the full IP policy carefully there, because there is a lot to be aware of. Next slide. So, also on the website, you can find a lot of helpful resources that are related to that exposure, state of blood lead testing now, what regulations you should be taking into account, development guidelines, and other project resources. All the links there are for informational purpose only and feel free to use them at your own discretion. Next slide, and last before we get to questions here, just how you can stay up to date. So on the website you can find a link to sign up for our challenge newsletter, where we'll be disseminating information or news over the next year, and you can also find there everything that we've talked about today. With that, I will hand it back over.

Carthur Wan:

So we'll now open up to questions and answers. We've received some during the call, but we also received questions throughout our registration process for this session, and we'll address some of those as well. I think, to begin with, we did receive, prior to this session as well, questions around what the main problems with current detection methodologies are, and again reiterating some of the points that we covered earlier, there is only one point of care test available that is clear waived and can be used by non-laboratory laboratory trained personnel, and the changes in the limit of detection. Sorry, the changes in the CDC reference value, bringing the limit of detection close to that reference value, is why current point of care testing is often unable to provide clear, actionable results at the newer lower reference value.

Alternative technologies with lower limits of detection are not currently available outside of lab developed tests and they usually require that venous blood draw, and point of care sampling also exacerbates the potential for contamination of a sample or test equipment. In the resources section on the challenge website, as Cameron mentioned, there are resources there bit dive deeper into the technical and engineering challenges for blood lead detection that we expect solutions will need to address. Jeff and some of our other subject matter experts have actually given some really great recent presentations that we'll look to post as well. We did receive a question as well on what is or isn't in scope of this challenge in terms of if people are expected to find new methodologies for current technologies or create new technologies entirely.

So the intent of a prize is intentionally not prescriptive about the type of methodologies and technologies used, so we hope to see eligible entrants submit a wide range of solutions that address the challenge's goal, consider all concept submissions requirements, and meet the evaluation criteria that are detailed on LeadDetectPrize.com. The evaluation criteria, we are looking for blood tests, given the

stated goal of the challenge. The prize aims to provide new point of care tests that can work within current clinical practice. While there are other analytes that may offer promise in the future, accelerating the time from concept through to real world impact is actually a priority for this challenge. Apart from that, no method or solution is explicitly out of scope. Entrants will be assessed by judges against each of the six Phase 1 evaluation criteria, and the most successful solutions based on this evaluation will be selected as Phase 1 winners and invited to Phase 2.

Cameron Fox:

I will jump in for this next question here. Someone asked about eligibility for institutions outside of the US. The short answer is yes. Individuals, teams, and institutions outside of the US are eligible. The only caveat there is that you will not be eligible if yourself, anyone on the team, or the entity is designated or sanctioned by the US Treasury Office of Foreign Asset Controls, but to be clear, that doesn't apply to countries. That is an individual designation, and I think we are sharing in the chat here some of the details of that. Next, we had a question about which technical factors are most important with regard to lead detection. So the judges will evaluate based on the six criteria that we ran through, and all of those will be equally weighted in their considerations.

Carthur Wan:

So we've also been asked what are the quantitative milestones for success? Again, the evaluation criteria are how solutions will be assessed in the basis for the winner and Phase 2 invitations. We provide the target performance metrics for Phase 1 that were mentioned earlier, and these are not explicit criteria themselves. Again, they serve as guidance for an eventual FDA cleared product. Whether or not a solution is able to currently meet any of these target performance metrics, we do expect solutions.

We'll carefully consider them and address how their concepts and development plans could meet them in the future. We've been asked, "Will applications be treated confidentially?" so all submissions will be treated with confidentiality, apart from the headline abstracts and certain entrant information that we may want to publish, and which are clearly delineated in the submission form and in the rules, terms, and conditions. In the concept paper itself, each entrant is asked to clearly delineate any confidential commercial information that's contained in submission, and that they wish to protect as proprietary data.

Cameron Fox:

We just got one asking, "Is the prize money supposed to be used to execute the concept?" While we would encourage the use of funds towards development of the concepts into products, prizes are intentionally non-prescriptive here. There are no explicit restrictions on what it can be used for, aside from what we shared about

grantees. So you do need to comply with any local, institutional, or other requirements or limitations for funds like this. If you're a federal grantee, you're going to have to look at that, but if that's not the case, then the money can theoretically be used for anything. Next, we have a question about what an acceptable level of accuracy is. Like we said in the target performance metrics, an ultimately approved product should aim for an ability to be within plus or minus two micrograms per deciliter or plus or minus 10% of the true blood lead value, whichever is greater.

Carthur Wan:

In terms of a question around whether there are any restrictions on leveraging published literature to support the proposal in terms of eligibility, so citations or references aren't likely to be a problem to provide background or supporting information, but for the proposed solution itself, the entrant must be the sole author or owner, or have the rights to use any copyrighted works that are part of the submission. So works must be wholly original with the entrant, or an improved version of existing work, but the entrant has sufficient rights to use and improve. That submission should not infringe on any copyright or any other rights of any third party of which the entrant is aware.

Cameron Fox:

So in terms of cost, what price per machine and price per test are you currently looking at, and what would be an acceptable range for an improved test? So we don't have an explicit target performance metric around the cost range but, like we said, accessibility is incredibly important here, and is one of the six evaluation criteria. I imagine that a successful submission would speak to intended points where it would work, and from there, consider the cost of the solution holistically, think about the analyzer itself, the consumables, what scale up would look like, and how that will translate to use in different environments.

We have another one about whether winners will get guidance on how to obtain FDA approval. So we do anticipate that Phase 2 will include technical assistance on a range of topics, and one of those will certainly be how to navigate regulatory considerations. This likely wouldn't include explicit FDA guidance outside of normal processes, but you can certainly expect some help there. And I would also encourage you to look at the resource pages of the website, as one of our sections is about that regulatory process.

Carthur Wan:

Just having a quick look through some of the others, we did have one. In terms of the current number of entities registered for a price, I don't think we can answer that right now. In terms of submitting multiple solutions, we'll need to, again, take that on notice and check in novel terms and conditions. In terms of current lab standards for testing for lead that could serve as the reference value, I think we would advise you to look to the

resources section that we have on the LeadDetectPrize.com website, and we will continue to potentially add new resources to that from Jeff and other members of our subject matter expert community.

Cameron Fox:

Yeah, and one thing to clarify there, because I think the question is phrased as, "What is the current lab standard that will serve as a reference value?" Just to be clear, when we talked about the reference value earlier, that was lowered from 5 to 3.5 micrograms per deciliter, this isn't a question of technical capability, point of care, or laboratory machines. This is based on a national survey of blood levels, where anything above the 97.5 percentile is a value of concern, and so the reference value here is a statistical measure, and not something that is comparing to, say, mass spectrometry or something that you're going to find in a reference lab, as they're certainly able to detect lower than we could feasibly expect most point of care to do.

We got a question about why this matters to public health authorities overall. What I would say there is that, while things like mass spectrometry or what you can find in labs, are very accurate, there is a behavioral economics cost here to both having a parent have to go to a venous blood draw. This is time-consuming. This is difficult for folks if you don't have a lot of resources. It's really difficult for a child as well, and that delay between actually getting the blood drawn and getting the test back is going to significantly drop off how much reaction you're going to have after. And so it's really, really important, and we see this in the literature, that there is something available at a convenient point of care, where someone is already being served, where they can quickly get a reading and then have it immediately.

Carthur Wan:

I think we may have been asked earlier as well, why specifically an FDA clear waiver clearance is a goal as opposed to lab developed tests. Again, I think adding Cameron's point, that is an important aspect from a public health perspective, in terms of having these tests available and accessible, and avoiding some of those implications in terms of having to seek lab laboratory services and to provide those tests. Additionally, I think as well, there's differences in capacity across healthcare systems, even within the US, and I think seeking FDA clear waiver as a clearance goal is partly towards addressing those discrepancies in a health capacity.

So we've been asked whether the proposed budget for development should align to the principal prize value for Phase 1. This is not a grant, in terms of what the prizes award at Phase 1. The prizes aren't meant to signal a budget in themselves. If you are putting forward the proposed development budget, we want to know what it will realistically take to develop your solution into a potential product. Prices don't typically fund the entirety

of development. We aimed more to accelerate progress and catalyze funding from other sources that may support the development of different solutions into products that can reach the market and create public health impact.

Cameron Fox:

In terms of the question about submitting more than one concept paper, I think we might've covered this, but we will need to consult CDC prize policies to understand this, and we can certainly give an answer after this, but don't have one right now. In terms of different groups from one university, this is not explicitly prohibited by the RTCs, though if the university is an entity, and multiple PIs want to submit, the university would likely want to make a decision about whether they want to allow that, but there is nothing prohibiting it.

Carthur Wan:

There is a query on, I guess, the involvement of NASA in this program. NASA Tournament labs, within the US government, actually provides unique open innovation capabilities that work across federal agencies to help run programs like this prize, and the CDC has partnered with NASA, who have been contracted luminary labs to design and administer this challenge, drawing upon our past experience across different prizes to accelerate scientific discovery. Are there any other questions that we have from the audience here today? Again, feel free to either pop them into the Q&A feature within the Zoom webinar, and again, if you don't want to, put it down alongside your name.` You can put these down as anonymous questions as well.

I think, in the past, we have been asked as well how the funding actually has to work in terms of if you do enter through an entity or institution, and whether or not these prizes actually have to run as grants through your grants offices, and have overheads and other requirements in that regard. I think the flexibility that a prize provides is that you do not usually have to adhere to the same reporting requirements, as a grant, and that you don't need to provide things like final reporting. Despite this, you will have to check with your specific institutions if you are applying on behalf of that entity, as your institutions may have their own policies that you need to adhere to. We do not require anything specific on our side though, in terms of things like final acquittals and reporting.

Cameron Fox:

We just got one asking if we're aware of any state level governments, whether public health labs, environmental, or other that are innovating in this low lead detection space. We are not. I believe this is a pretty first-of-its-kind prize. If anyone else has any other information, I'd be surprised, but I don't think there's anything at the state level that is analogous to this right now. Do we have to include the lead detection result in Phase 1

submissions? I'm assuming you're talking about hard data on a specific testing prototype.

The short answer is no. We want to understand your scientific rationale, how you plan on getting there, and what you estimate will be possible, but we don't expect to have a fully fleshed working machine by the end of January. We're really understanding who has the best plan to get there with good backing. Any data that you do have is wonderful and will be a bolster, but it is certainly not a requirement. Like we said in the target performance metrics, these are our north star, but not what we are anticipating being ready by January.

Carthur Wan:

Do we have any additional questions to [inaudible 00:46:10] today? Again, there will be opportunities as well to engage through our contact, through our contact email hello@LeadDetectPrize.com, if other questions do arise throughout as you engage with the materials on LeadDetectPrize.com around the rules, terms, and conditions and eligibility requirements. We had one last question as well, around whether PIs from universities and companies can submit in collaboration. We would encourage collaborations between both academic and commercial entities.

There's no restriction against that. In terms of the logistics of when the recording will be available, we'll seek to get that out as soon as possible. It'll likely be within approximately a week or so. I think if we have no further questions for today, we'd like to thank you all for joining us. We hope this has been informative, inspired you to contribute your expertise, and spread the word about this important challenge. So to stay up to date, you can use the QR code that's on the screen to sign up for the Lead Detect Prize newsletter. As noted, the webinar recording will be publicized through that newsletter as well, so you'll be able to know when it comes up.

If you're interested in entering, we'd encourage you to register your team on the challenge platform, and if you'd like to help us get the word out about the prize to people you may know, who would be interested in entering, we'd appreciate the support, and have some materials and social media post and communications that are prepared to make it easier for you to share. As I noted before, if you have any other queries that arise, as you're considering the prize, you can contact us at hello@leaddetectprize.com, but otherwise, thank you all for joining us today, and have a great rest of your day.

Cameron Fox:

Thanks, everyone.