



LONGITUDE PRIZE

PRIZE RULES

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Antibiotic resistance is a growing and severe problem that threatens to reverse many of the achievements of modern medicine. At the end of June 2014, the British public voted for antibiotics to be the focus of the £10 million Longitude Prize®. The race is now on to develop a new test to detect and understand infections, to help ensure the right antibiotics are used at the right time.

£8 million will be awarded to the competitor that solves the challenge and up to £2 million may be used to support promising entries along the journey.

CHALLENGE STATEMENT

The Longitude Prize will reward a competitor that can develop a transformative point-of-care diagnostic test that will conserve antibiotics for future generations and revolutionise the delivery of global healthcare. The test must be accurate, rapid, affordable, easy-to-use and available to anyone, anywhere in the world. It will identify when antibiotics are needed and, if they are, which ones to use.

The Longitude Prize is open for anyone to compete, and we welcome your participation. The more people who participate, the more likely it is that the solution will be found and progress made to tackle this urgent global problem.

The final decision to award the Longitude Prize and associated grants will be made by the Longitude Committee, which is composed of leading figures in the field of science, technology, and healthcare and chaired by Astronomer Royal Lord Martin Rees. The Committee will make their decisions based upon the recommendations of the Prize Advisory Panel, which is composed of experts in the fields of antibiotic resistance, diagnostic technology and global health and development.

You can register for and enter the Longitude Prize at any time, and the competition will close when the Longitude Committee decide to award the Prize. The Longitude Committee reserves the right not to award the money if no team meets the criteria as outlined in Part 3 of this document.

The Longitude Prize is being supported by Innovate UK and is managed by the Challenge Prize Centre at Nesta, an innovation foundation.

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PART 1

WHAT IS THE LONGITUDE PRIZE?

LAUNCH OF THE PRIZE

The Longitude Prize was launched on the 300th anniversary of the original Longitude Act of 1714, which encouraged innovators to help the British Government to find a method for measuring longitude at sea by offering a £20,000 prize.

In the summer of 2013, the new Longitude Committee chaired by the Astronomer Royal Lord Martin Rees came together to discuss the most pressing global challenges of our time. In consultation with some of the UK's leading experts, the government and the public, Nesta, the innovation foundation, presented six possible challenges that could be the focus of a new Longitude Prize. These challenges were:

 **FLIGHT** How can we fly without damaging the environment?

 **ANTIBIOTICS** How can we prevent the rise of resistance to antibiotics?

 **DEMENTIA** How can we help people with dementia live independently for longer?

 **PARALYSIS** How can we restore movement to those with paralysis?

 **WATER** How can we ensure everyone can have access to safe and clean water?

 **FOOD** How can we ensure everyone has nutritious, sustainable food?

The British public had the opportunity to vote for the challenge that they thought should become the focus of the new Longitude Prize. Voting took place between 22 May and 25 June 2014 and after all of the votes were received '**ANTIBIOTICS**' was announced as the winning challenge on the BBC One Show.

Following the public vote, the Prize Advisory Panel, the Prize's judging panel, were formed, bringing together the foremost experts in antibiotic resistance. They, along with the Longitude Committee and with expert input, decided that the new Longitude Prize should seek to innovate new point-of-care diagnostic tests to help tackle antibiotic resistance.

AIM OF THE PRIZE

The Longitude Prize aims to incentivise the development and production of a transformational diagnostic that will enable clinicians and patients around the world to make more informed choices about the use of antibiotics, as one element of a global, interdisciplinary effort to address the problem of antibiotic resistance.

In order to encourage innovation in all aspects of diagnostic development for point-of-care use, the Longitude Prize will not narrow its focus further to a particular subset of diagnostic tools or clinical problems. Developing a new diagnostic tool requires ingenuity, not only in devising methods of detection, but also in determining a clinical context in which a diagnostic tool can have the greatest impact. It will be up to the competitors in this challenge to determine the scope of their proposed diagnostic test.

The Longitude Prize invites a variety of proposals from a wide range of specialist fields and sectors: from academic groups through to commercial companies, from biomedical scientists through to material engineers, from synthetic and molecular biologists through to physicians, specialist clinicians, and completely unexpected sources.

The Longitude Prize is ambitious. We are not looking for incremental changes to existing technologies but for transformative solutions that will revolutionise the prescribing and use of antibiotics globally. Our vision is that the Longitude Prize will only be awarded to a test which has the potential to positively influence treatment decisions in the maximum possible number of occurrences where antibiotics are taken.

PART 2

HOW TO ENTER

PRIZE STRUCTURE

The Longitude Prize opened to competitors on the 18 November 2014 and will run until a winner meets all the criteria for the prize, or to at least 31 December 2020. The Longitude Committee reserves the right to shorten or extend the duration of the prize in its sole discretion.

The prize fund totals £10 million, of which £8 million will be awarded to the competitor who manages to solve the challenge. At the discretion of Nesta and the Longitude Committee, up to £2 million may be used to support promising submissions along the journey including as part of the Longitude Discovery awards and Longitude Boost grants.

The Longitude Committee reserves the right not to award the prize if no team meets the criteria. For further details on the prize timeline and deadlines please see the timelines in **PART 4**.

All entries will be subject to the Longitude Prize Terms & Conditions. Please read the Terms & Conditions carefully before you enter.

REGISTRATION

To compete in the Longitude Prize you must first register by completing the registration form on the **Longitude Prize website**: <http://www.longitudeprize.org/>

By registering for the Prize you will be able to formally compete in the Longitude Prize and you will receive key information and updates regarding the Prize.

The registration form asks for information about your team including the team name, leader and contact details. If you are entering the Longitude Prize as part of a team, you must nominate one person as team leader. This person is responsible for making sure that all other team members are aware of and comply with the Terms & Conditions and this document. The form also asks for a summary of the entry that you are developing, details of your product and other questions pertaining to the criteria of the Longitude Prize.

Some of the information provided in the registration form, which has been agreed with you, will be made publicly available on the Longitude Prize website.

You can register at any time. We encourage you to register at an early stage so that we can showcase your progress towards winning the prize on the Longitude Prize website.

Once you have registered, a link to our online application form will be made available to you. You will receive this within five working days of receipt of your registration form.

APPLICATION

It is the responsibility of each team or individual to submit a complete application form when they believe that their innovation meets the criteria for the Prize. Supporting evidence will be required to verify the claims that you make in the application form.

You can see the timeline for submission of entries to the Longitude Prize in **PART 4** of this document. The application form is completed online and supporting evidence will be uploaded to this secure online system. Please identify any confidential or sensitive information included in your entry. Only prize organisers, assessors and the Prize Advisory Panel will be able to access this information and all individuals that can access, view or judge this information will be subject to strict confidentiality, including non-disclosure agreements.

WHO CAN PARTICIPATE?

Anyone of any age and any organisation may enter the competition as long as you meet the **Eligibility Criteria** below:

The team is able to demonstrate that in winning the Longitude Prize it would deliver direct economic growth or benefit or social benefit in the UK.

To demonstrate such benefit the team must:

Include a member who has a presence in the United Kingdom, meaning an office in the UK, affiliation with a UK Company or partnership with a UK organisation or institution, and meet one of the following requirements:

- a. carry out manufacturing and/or design of the winning solution in the UK, or
- b. lab test or showcase the winning solutions in the UK, or
- c. use some other means agreed in writing with Nesta and Innovate UK before participating in the Longitude Prize

OFFICIAL LANGUAGE AND CURRENCY

LANGUAGE

The official language of the prize is English. All communications and entries must be made in English.

CURRENCY

The official currency is pounds sterling. All monetary values are in pounds sterling unless otherwise stated.

PART 3

WHAT YOU MUST DO TO WIN THE LONGITUDE PRIZE

Judging of the Longitude Prize will be based on the criteria and requirements set out below. In your application form you must provide information that outlines how your innovation meets each of these criteria. You must also provide detailed evidence that validates each of these claims.

Nesta may refine and clarify the criteria and requirements as appropriate over the course of the Longitude Prize in-line with the overarching aim of the prize. Any changes will be communicated to all registered participants.

The winning entry must fully meet the requirements set out in the criteria and Challenge Statement.

CHALLENGE STATEMENT

The Longitude Prize will reward a competitor that can develop a transformative point-of-care diagnostic test that will conserve antibiotics for future generations and revolutionise the delivery of global healthcare. The test must be accurate, rapid, affordable, easy-to-use and available to anyone, anywhere in the world. It will identify when antibiotics are needed and, if they are, which ones to use.

CHECKLIST

1. NEEDED	<p>Focused on a globally occurring problem</p> <p>The test must improve the targeted use of antibiotics for one or more common globally occurring infections (including in the UK) by:</p> <ul style="list-style-type: none"> – Ruling out unnecessary antibiotic use, <p>AND/OR</p> <ul style="list-style-type: none"> – Providing all of the necessary information to identify an effective antibiotic or combination of antibiotics.
	<p>Able to improve antibiotic treatment decisions</p> <p>The test must address the described problem appropriately so that it improves antibiotic treatment decisions and public health.</p> <p>The test must improve on currently available existing diagnostic approaches.</p>

<p>2. ACCURATE</p>	<p>The test must be accurate enough to eliminate harmful treatment decisions, inform more targeted antibiotic use, and give users the confidence to act upon its result.</p>
<p>3. AFFORDABLE</p>	<p>At forecasted full scale manufacture the test, including any instrumentation, must be affordable for purchase and use in its intended market(s).</p>
<p>4. RAPID</p>	<p>The time from sample collection to reporting of the result to the treatment decision-maker must be less than thirty minutes.</p> <p>The test's time to result must be in line with current clinical practice in its chosen clinical pathway or competitors must lay out how they intend to overcome this issue.</p>
<p>5. EASY-TO-USE</p>	<p>Globally applicable</p> <p>The test must be suitable for point-of-care use in all global healthcare settings where the test could be used to inform treatment decisions.</p>
	<p>Minimally reliant on healthcare resources</p> <p>The test must require minimal healthcare resources and training to be used effectively and safely.</p>
	<p>Easy-to-use and Interpret</p> <p>The test must be easy to use and interpret safely and effectively, in the settings and locations where it will be used.</p>
<p>6. SCALABLE</p>	<p>Ready for manufacture and distribution</p> <p>There must be a feasible product commercialisation plan for full-scale manufacture and distribution.</p>
	<p>Original</p> <p>You must take reasonable steps to find out whether your technology infringes on the intellectual property rights of others.</p>

7. SAFE	The risks associated with a test will be judged against the benefit it can provide.
8. CONNECTED	Tests which have an in-built data recording and transmitting capacity will be favoured. A test does not need to have this capacity in order to win the prize.
LEVEL OF DEVELOPMENT REQUIRED	The test must be a design-locked, optimised prototype, which has undergone performance evaluation in preparation for regulatory approval. In addition, you should be able to indicate impact in your chosen clinical pathway(s).

A. NEEDED

A1. FOCUSED ON A GLOBALLY OCCURRING PROBLEM

This section is to ensure that the submitted diagnostic test's target infection(s) represent a genuine pressing global problem, particularly with respect to antibiotic resistance. As well as identifying the existence of the problem, you should explain the drivers behind it.

You should base your problem description on good evidence. Statistics and definitions used should be provided, referenced, and clearly explained.

WHAT YOU NEED TO DO TO WIN

The diagnostic test will improve the targeted use of antibiotics for common globally occurring infections by:

- Ruling out unnecessary antibiotic use;

AND/OR

- Providing all of the necessary information to identify an effective antibiotic or combination of antibiotics.

In each case the diagnostic test must fulfil a global and UK need.

A diagnostic test may do this in a number of ways:

- differentiate between viral or bacterial infections; or
- it may identify the causative pathogen; and/or
- its antibiotic susceptibility and resistance.

The Longitude Prize is ambitious. We are not looking for incremental changes to existing technologies but for transformative solutions that will revolutionise the prescribing and use of antibiotics globally. Our vision is that the Longitude Prize will only be awarded to a test which has the potential to positively influence treatment decisions in the maximum possible number of occurrences where antibiotics are taken.

Exceptions may be made from the stipulations above if competitors can provide a compelling, well-evidenced argument for the severity of the infection(s) that their diagnostic test targets. For example, such an argument may be based on the fact that a disease is rapidly proliferating, or that growing antibiotic resistance threatens to make a treatable infection extremely harmful.

WHAT YOU NEED TO TELL US

You must provide a clear explanation of why a diagnostic is needed and the potential it has to reduce unnecessary antibiotic use. You will need to tell us about the problem created by the pathogens and infections being tested for, and explain how this contributes to the growth of antibiotic resistance, therefore demonstrating there is a clear need for a solution. This information, along with a description of how the test will specifically improve antibiotic treatment decisions (in the next section), will allow our judging panel to see the potential the diagnostic test has to make a positive impact. We will accept clearly referenced papers or studies that support claims for the burden of specific infections globally.

- **Which infection(s) does your diagnostic target?**
 - Give the global incidence of new cases per year for the target infections based upon the best available data (please reference clearly).
- **Explain how the targeted infections represent a pressing need in relation to antibiotic resistance and discuss the evidence that a diagnostic test is the right approach.** We favour a global perspective and expect this answer to include a description of the situation in multiple locations globally in order to demonstrate that there is substantial need for an intervention. Please attach and clearly label any supporting data or studies that demonstrate disease burden, etc.
 - Outline the key problems that produce a need for a diagnostic and why it is important with regard to the bigger picture of antibiotic resistance globally.
- **Describe any relevant existing diagnostics (point-of-care and lab based) and explain why they do not adequately address the problem.** Outline the best available and the most commonly used alternatives.
- **Describe any social and cultural factors which drive the problem(s).** Please include behavioural drivers of the problem across the different locations where the target infection(s) has a significant incidence, for example, end users buy antibiotics direct from pharmacies without prescriptions, existing diagnostics are too expensive for use in primary healthcare settings, sample collection methods are not accepted locally.

A2. ABLE TO IMPROVE ANTIBIOTIC TREATMENT DECISIONS

This section is to ensure that the submitted diagnostic test will effectively address the problem outlined above. This means not just providing a diagnostic test which targets a burdensome infection(s), but also ensuring that it will actually influence antibiotic use by addressing the particular factors which influence treatment decisions.

WHAT YOU NEED TO DO TO WIN

The diagnostic test **must** address the described problem appropriately so that it improves treatment decisions and public health.

The diagnostic test **must** improve on existing diagnostic approaches that are available to purchase at the time of submission of your application to the Longitude Prize.

WHAT YOU NEED TO TELL US

Explain how the test will specifically address the outlined problem(s). This should include details of:

- **Existing diagnostics** – How the submitted test improves upon existing diagnostics in this field against the remaining criteria outlined in this document. Please outline the best alternative and most commonly used alternatives (either point-of-care or lab-based testing);
- **Improving targeted antibiotic use** – How the submitted diagnostic test is intended to improve targeted use of antibiotics;
- **Treatment decision** – How the test will fit into or change the treatment decision process. If the process varies across different settings, please describe the most widespread processes. Outline a patient pathway for the diagnostic test; this can be a traditional flowchart or another graphic representation. This will demonstrate at what point the diagnostic test can be used, and how the test affects treatment decisions. The pathway must show a journey from patient presentation to final intervention;
- **Behaviour and cultural practices** – How the test addresses the behavioural drivers of the problem across the different locations at which the infection has significant incidence, for example, if antibiotics are regularly bought from pharmacies without prescriptions, the diagnostic test should be suitable for sale in pharmacies and self-use. How will external factors, which will impact the efficacy of your test, be addressed?
- **Feasibility** – Research which demonstrates that the diagnostic test will be used and have an effect in its intended-use setting. This research is likely to be qualitative and could include focus groups and interviews with the relevant communities. This evidence is particularly important when a submitted diagnostic test either has a novel operation or will be used in a novel setting.

B. ACCURATE

Accuracy is an essential characteristic of diagnostic tests. An inaccurate diagnostic test may result in low uptake and incorrect treatment decisions, with potentially harmful consequences. Sensitivity and specificity are vital components of accuracy.

- **Sensitivity** is the probability that patients with the specific infection will have a correct positive result using the test.
- **Specificity** is the probability that patients without the specific infection will have a correct negative result using the test.

This information is combined with infection prevalence in the studied population to give predictive value:

- The **positive predictive value** is the probability that a test result accurately indicates the presence of infection.
- The **negative predictive value** is the probability that a negative result accurately indicates the absence of infection.

WHAT YOU NEED TO DO TO WIN

The test **must** be accurate enough to eliminate harmful treatment decisions, improve targeted antibiotic use, and give users the confidence to act on its result in the global settings and locations where the test will be used. There are no uniform values for minimum accuracy for the Longitude Prize because acceptable accuracy varies between infections and populations.

WHAT YOU NEED TO TELL US

You must submit;

- **Sensitivity and specificity values** for your diagnostic test and the positive and negative predictive values. Please include a summary of how you have calculated these figures, including details of the samples used and patient cohorts. You must also attach supporting material with full details of the relevant trials that you have undertaken to calculate these figures.
- **A description of the range of analytes** over which there is an accurate result and which standard your diagnostic accuracy is measured against.
- **A summary of any local conditions**, such as diet, comorbidities, or anything else, which affects the accuracy of your test.
- **A description of how the accuracy values of your test are high enough to improve targeted antibiotic use** whilst eliminating harmful treatment decisions. Evidence should also be provided that details how the accuracy of your test gives users the confidence to act on its result.

C. AFFORDABLE

Affordability covers the **price point** of the diagnostic test in the relevant global markets.

To be affordable, the price of the test must reflect value for money to the intended users, whoever they might be (for example, patient, doctor, health service).

The **manufacturing and operational costs** of the diagnostic test will also be considered.

WHAT YOU NEED TO DO TO WIN

At forecasted full scale manufacture the test must be affordable for purchase and use in its intended global markets.

A test will be considered affordable if the price of the test:

- is affordable in the intended settings of use and reflects value for money for the intended users.

You should review the price point alongside the cost of unnecessary antibiotics and other treatment costs that the test might save in the relevant global markets, and the next best diagnostic technique in the different contexts in which the test is going to be used. This comparison demonstrates how the innovation provides value for money and whether it is genuinely affordable.

WHAT YOU NEED TO TELL US

You must demonstrate to the judges through written evidence and forecasting that your product will be affordable at scaled production. You must show an understanding of customer affordability or competitive pricing requirements. We encourage you to have direct contact with customers to understand their true needs and hear their sensitivity to costs directly, and to have thoroughly researched competitors' product pricing in the marketplace.

- **Give the projected unit cost at production scale of 10,000 units** with a breakdown of the unit costs including the estimated costs of production labour, direct materials, process, overheads, primary and secondary packaging, outside processing and all other relevant details. Please specify the manufacturing processes involved. This can be built around existing processes where relatively good historical cost data should exist. On occasion, new manufacturing processes will need to be considered. Data will need to be gathered as a basis for creating or extending the product cost model for the new process or processes.
- **Cost per reportable result.** As well as the cost of the test, this figure should take account of any additional materials and processes needed to perform the test, such as extra syringes, quality control, or calibration.
- **Give the price point(s) of the target market(s), along with a description of the target market.** Attach the supporting material for this calculation. Please provide comparative data in order to explain how the pricing model is affordable.

D. RAPID

WHAT YOU NEED TO DO TO

In order to win the Prize, tests **must** be able to give a result to the user in less than 30 minutes. In addition, the time to result must be suitable for the relevant clinical treatment pathway. Time to result is constituted of the time from the beginning of sample collection to the delivery of the test result to the user of the test.

WHAT YOU NEED TO TELL US

Give the time to result from the beginning of sample collection to reporting of the result to the end-user, as well as the breakdown times for each step of the process (for example, sample collection, sample preparation, etc.). Attach details of any evidence which supports your claims. The submitted values should reflect use in the intended setting, for example, if it's intended for patient self-use, times should not be based upon use by a trained laboratory technician.

In many instances, depending on the context, a test may need to be significantly quicker than 30 minutes to be clinically useful. You must explain how the time to result of your test will be appropriate for its intended use. We reserve the right not to award the prize if the time-to-result of your test is not appropriate for the intended-use setting, even if it is below 30 minutes.

E. EASY-TO-USE

E.1. GLOBALLY APPLICABLE

To win the Longitude Prize a diagnostic test **must** be able to be used safely and effectively at point-of-care settings globally, including in low and middle-income countries.

The innovation **must** be suitable for use in a range of healthcare settings.

It **must** be suitable for use in healthcare settings where a large number of treatment decisions are made with regard to the relevant infection(s). Requirements to help achieve the settings criterion are outlined below.

E2. MINIMALLY RELIANT ON HEALTHCARE RESOURCES

WHAT YOU NEED TO DO TO WIN

A diagnostic test **must** require minimal healthcare resources, as set out below. A test which requires fewer healthcare resources to be used safely and effectively will be favoured.

WHAT YOU NEED TO TELL US

You **must** provide relevant information under each of the categories below. Healthcare resources include personnel and expertise as well as physical resources. Alongside this, you should outline how these specifications match the resources available in the intended-use settings. Where supporting material is available, such as temperature stability trials or user training studies, this should be attached and clearly labelled.

- **Calibration requirements and controls.** The test should provide an accurate result without calibration.
- **Specimen type, volume, and collection method.** Collection methods must be non- or minimally invasive, they must be able to be performed without specialist equipment, and they must minimise pain or be painless.
- **Sample preparation (steps, biosafety, precision required, time sensitivity).** This process must be fast, automatic, contained within the device, and involve a minimal number of steps.
- **Waste disposal (safety, ease, environmental acceptability).** Waste must be minimised and must be disposed of without posing a safety or environmental risk.
- **Reagents required (availability, inclusion).** The reagents must be widely and cheaply available or be included as part of the diagnostic test.
- **Storage/stability (shelf life inc. reagents, temperature stability, humidity stability).** Diagnostic tests and their reagents must have long expiration dates, and they must be physically robust. They must be stable across a wide range of temperatures (high and low) and stable over wide humidity range (heat stable and humidity stable). It must be able to withstand short-term transport stress i.e. environmental extremes experienced during transportation.
- **Instrumentation (maintenance requirements, replacement cost, size, shock resistance).** Any instrumentation must require no or minimal maintenance, require no specialist expertise to maintain, be cheap to maintain, and be physically robust so as to minimise the need for maintenance and repair.
- **Power requirement.** Any instrumentation must not be reliant on mains power to function. It must require minimal power which would be available from temporary or mobile power sources such as batteries or solar cells.
- **Training required (mode, level, and length).** No training or minimum training should be required, and effective instruction must be given via simple text or pictorial instructions which would take account of language and literacy considerations in the target markets.
- **Intended user (trained laboratory worker, primary care doctor, untrained patient, etc.).** The diagnostic test must be capable of being used safely and effectively by minimally trained primary care workers or even the patients themselves.
- **Portability and size.** The diagnostic test must be able to be carried easily, safely, and comfortably by a single person, and be of a suitable size for desktop storage and use. Tests that are lighter and smaller will be favoured.

Exceptions may be made under exceptional circumstances from the requirements above if you can provide a well-evidenced and compelling argument for the need to do so.

E3. EASY-TO-USE AND INTERPRET

WHAT YOU NEED TO DO TO WIN

The test **must** be easy to use and interpret effectively and safely in its intended-use setting. This means that diagnostic tests should ideally be integrated, closed, sample-to-answer systems with automated data analysis and result presentation. Additionally, the test should be adapted to take account of any particular behavioural and cultural practices.

WHAT YOU NEED TO TELL US

You must submit;

- A description of conditions of use that might affect test use safety or effectiveness, including behavioural and cultural practices;
- A summary of the characteristics of intended-use environments that could impact use (for example, glare, vibration, ambient noise, etc.). Any environments for which the test is unsuited should be stated;
- The known use problems with previous models of the same test (as applicable) or problems with similar types of medical devices;
- Any design modifications of the current device that were specifically developed in response to use problems in the field;
- A synopsis of any previous usability testing, including how the testing was conducted, the test results, and a discussion of all performance failures and critical assessments by test participants; and
- The formative evaluation methods used key results of those evaluations and any modifications that were implemented to the user interface design in response to the results of the formative evaluations.

F. SCALABLE

You **must** outline how you will realise the potential for your diagnostic test to have a significant global impact by describing how you will scale up to large scale manufacture and distribute and sell your test where it is needed.

WHAT YOU NEED TO DO TO WIN

You **must** have a feasible plan for delivering the diagnostic test at an affordable price (*Refer to C. Affordable*) to all of the worldwide settings where it is needed. This includes plans for full-scale manufacture and global distribution including, where appropriate, pricing structures and collaborations with partners. You must also consider whether your technology infringes the intellectual property rights of others and you must have an intellectual property strategy which is appropriate for allowing affordable and timely access to the test by end-users. If you do not have in place the necessary intellectual property rights or agreements to develop or exploit your product you may not be awarded the Longitude Prize.

WHAT YOU NEED TO TELL US

You **must** provide a clear product commercialisation plan including details on the following points.

- **How will you move to quality assured full-scale manufacture?** Give details of timelines, milestones, partners, suppliers and processes.
 - **How will you distribute the diagnostic test to the settings in which it is needed, including low-income countries?** Give details of costs, partners and processes.
 - **How will you ensure the long-term sustainability of the solution in different marketplaces?** You should consider service and repair needs and local skills.
 - **How will you meet regulatory approval so that your test can be sold in the nations where it is needed?** Give details of timelines, dealings with regulatory agencies and how you meet regulatory requirements.
 - **Please indicate your access strategy to ensure access in countries with differing abilities to pay.**
 - **What is your competitive landscape?** What are the solutions you need to compete against in the marketplace (product features and providers)? What similar products can be expected from the development pipelines of other companies in the near and mid-term future? Which will be the 'unique selling points' of your product vs. present and upcoming competitors in the market (please break down by the different markets the solution is supposed to serve)? *(Refer to A. Needed)*
 - **Have you taken any steps towards protecting your intellectual property?** Where is it protected? Where do you intend to protect it? Are you aware of or have you explored whether your product infringes on the intellectual property rights of others (freedom to operate)?
 - **Have you structured your intellectual property strategy such that end-users will be able to affordably and easily access your test?** The intellectual property strategy for the diagnostic test should not hinder end users from being able to access the test in an affordable and timely fashion.
 - **What are the risks involved in the product commercialisation plan and how will they be mitigated?** How do you address external factors that will impact on your test moving to scale?
-

G. SAFE

It is your responsibility to adhere to applicable safety and regulatory legislation. This risk framework is only designed for use in the Longitude Prize. This risk assessment will allow us to judge the anticipated benefit of a diagnostic test against the risk it poses. Risk is the combination of the probability of occurrence of harm and the severity of that harm.

WHAT YOU NEED TO DO TO WIN

The risks attached to your test **must not** outweigh its benefits.

WHAT YOU NEED TO TELL US

For example;

You must submit your own risk assessment based upon the framework outlined below. Using this framework to justify your decisions, you must separately class the individual and public health risks associated with your diagnostic as low, medium or high.

RISK FRAMEWORK

- Clinical importance of test result to the diagnosis (sole determinant or one of several).
- Tasks or use scenarios that are most likely to be associated with use error that could cause clinical harm to the patient or the user.
- The likelihood of false results given the clinical importance of a test to diagnosis, setting of use, and expertise of the likely user.

H. CONNECTED

In-built automatic data recording and transmission capability is not a necessity for winning the Prize. Rather a diagnostic test which has this capability will be favoured over one which does not.

WHAT YOU NEED TO TELL US

You must submit the details of any surveillance capacity built in to the test, including how it records and transmits information and the resources it requires to do so (i.e. mobile phone, user input, training), the surveillance system that it feeds into, interoperability and the data interface protocol.

LEVEL OF DEVELOPMENT REQUIRED

Before entering the Longitude Prize you must have produced functional test units that meet all of the criteria outlined above. Your test must be a design-locked, optimised prototype which has undergone performance evaluation in preparation for regulatory approval. If your test is selected for further testing you will be required to supply a number of test units for full appraisal.

You must submit laboratory data that demonstrates the performance of your test. In addition, you must submit data that indicates that your test will have adequate impact in your chosen clinical pathway(s). Published data is preferred.

PART 4

THE JUDGING AND ASSESSMENT PROCESS

You can register for and enter the Longitude Prize from 18th November 2014.

You can register for and enter the Longitude Prize from 18th November 2014. The competition will close when the Longitude Committee agree that a competitor has met all requirements set out in the criteria and decide to award the prize. If no entry is judged by the Longitude Committee to have met all of the requirements set out in the criteria or the aims of the Longitude Prize, the competition will run to at least 31 December 2020. The Longitude Committee reserves the right to shorten or extend the duration of the prize in its sole discretion.

LONGITUDE COMMITTEE

The Longitude Committee features some of the leading experts from across the scientific world. They will make the final decision as to which entry should win the Longitude Prize.

Members will declare any relationships or interests which they have which might give rise to an actual or perceived conflict. Any conflicts that arise will be handled appropriately.

The membership of the Longitude Committee can be found on the Longitude Prize website.

PRIZE ADVISORY PANEL

The Prize Advisory Panel provides expert independent scientific and technical guardianship for the Longitude Prize. Drawing on their unique expertise they will make judgements and recommendations to the Longitude Committee regarding the allocation of awards to Prize competitors and provide advice about the design of the prize. The membership of the Panel was nominated by Nesta and approved by the Longitude Committee. You can find the list of Prize Advisory Panel members on the Longitude Prize website.

All members of the Prize Advisory Panel are required to sign a non-disclosure agreement. Members declare any relationships or interests which they have which might give rise to an actual or perceived conflict. Panel members will not participate in Prize Advisory Panel discussions or other activities where they are subject to an actual or perceived conflict of interest.

ASSESSMENT

We will undertake a rigorous assessment of all entries to the Longitude Prize to see whether they meet the criteria to win the prize, as set out in this document.

You can register for and enter the Longitude Prize from 18th November 2014 and entries can be submitted at any time, but they will only be reviewed and assessed every four months after each deadline has passed.

DEADLINES

The rolling deadline rounds for entry into the Longitude Prize are provided below:

2015 – 31st May, 30th September

2016 – 31st January, 31st May, 30th September

2017 – 31st January, 31st May, 30th September

2018 – 31st January, 31st May, 30th September

2019 – 31st January, 31st May, 30th September

2020 – 31st January, 31st May, 30th September

REVIEW

Once you have submitted your application it will be reviewed by expert assessors to determine whether your entry meets or is capable of meeting the criteria to win the Longitude Prize.

Your entry will be unsuccessful if:

- Your application form is **incomplete**,
- You **do not satisfy the eligibility criteria** set out in the ‘Who can participate?’ section of this document,
- Your entry is **out-of-scope** for the prize,
- It is clear that your entry **does not meet or is not capable of meeting the Prize criteria**, set out in this document.

If your entry is unsuccessful, you will be informed of this decision by e-mail within two months of the relevant application deadline. You will also receive short feedback on your application that explains why it was unsuccessful. No other correspondence will be entered into.

Entries that have been reviewed by the Longitude Prize team at Nesta and that are judged to meet or are close to meeting the prize criteria will be sent to the Prize Advisory Panel for further assessment. At this stage, if you are successful you may be asked to provide further information to support the Prize Advisory Panel’s assessment.

PRIZE ADVISORY PANEL

The Prize Advisory Panel meet every four months with the timing of the meetings arranged so that they are within three months of each entry deadline. At these meetings they will review the entries referred to them by the Longitude Prize team at Nesta.

INTERVIEW

If the Prize Advisory Panel decides that from your application form and supporting evidence your entry meets the criteria to win the Prize, you will be invited for an interview with a sub-group of the Prize Advisory Panel. The interview will take place within six weeks of the Prize Advisory Panel’s decision. If the Prize Advisory Panel decides that your entry does not meet the criteria, your entry will be unsuccessful. The Panel will provide you with feedback explaining their decision.

At the interview the Panel will ask questions based on the details provided in your application form and supporting evidence. In advance of the interview the Panel may request further information or evidence to clarify the claims made in your application.

Following the interview, the Panel may agree to invite you to take part in independent testing and modelling. You will be informed of the Panel's decision within six weeks of your interview.

TESTING

Testing and modelling will take place over the six to twelve months following the Prize Advisory Panel's recommendation. You must provide an appropriate number of test units for testing.

Independent testing and modelling consists of:

- 1. Performance testing** – In order to verify your claims, submitted diagnostic tests will be independently tested for performance. This testing will take the form of a laboratory-based retrospective trial using archived specimens from a target population.
- 2. Impact modelling** – If deemed necessary by the Prize Advisory Panel (in its sole discretion), a custom model will be constructed based upon an intended-use setting and the diagnostic test characteristics to forecast the effect of the diagnostic test upon treatment decisions. This will give an indication of the ability of the diagnostic test to reduce inappropriate antibiotic use in real-life settings.

If considered necessary, Nesta will ask independent experts to verify or calculate manufacturing cost, price point and any other relevant information to validate the current and future affordability of your test. Depending on the evidence provided as part of the application form and the supporting evidence, we reserve the right to forgo all or any of this testing. We reserve the right to conduct further testing, in addition to what is set out above, if required to validate your claims. The form and extent of assessment and testing will be determined by Nesta at its sole discretion.

AWARDING THE PRIZE

If the Panel judges that the testing supports your claims and that the submitted test therefore fully meets the Prize criteria, they will recommend to the Longitude Committee the award of the Longitude Prize. If in the opinion of the Panel, the testing does not sufficiently support your claims, your application will be unsuccessful. Detailed feedback will be provided explaining why the entry did not meet the necessary requirements.

LONGITUDE COMMITTEE

The Longitude Committee will make the final decision as to whether your entry meets the criteria and Challenge Statement.

The Longitude Committee meets twice a year. Recommendations made by the Prize Advisory Panel will be heard at the next Committee meeting following the Panel's recommendation.

If the Longitude Committee agree that your entry meets the criteria and Challenge Statement in full you will be awarded the Longitude Prize.

The winning team must spend their prize money to develop and market their product as proposed in their winning entry so that it can create maximum global benefit and achieve the aims of the Longitude Prize. This requirement may be relaxed if the winning team can prove to the Longitude Committee that they will be able to create maximum global benefit and achieve the aims of the Longitude Prize without further development, for example, show that it will be utilised for public benefit through openly licensing their IP or demonstrating sufficient funding to commercialise their product.

The Longitude Committee reserve the right to not award the prize money if, in their opinion, no entries satisfy the criteria and aims of the Prize. If they choose not to follow the Panel's recommendation, they shall provide comprehensive feedback to you and to the Panel as to why they have not awarded the Prize.

RESUBMISSION

If your entry is unsuccessful, you will be able to resubmit an improved entry to the Longitude Prize six months after receiving your rejection from the Longitude Prize. All submissions must be made before the final deadline.

APPEALS

If you disagree with the decision made at any stage of the assessment process you can contact the Longitude Prize on the details provided at the end of this document. We will respond to your enquiry within thirty working days. If our response is unsatisfactory we will provide you with further information about how you can escalate your appeal.

INTELLECTUAL PROPERTY

The Longitude Prize winner will retain all intellectual property rights. However if the competitor fails to develop and exploit their rights within five years of the award of the Prize, a license will be granted to Innovate UK or Nesta to develop and exploit the intellectual property rights (see Terms and Conditions for more details).

CONFIDENTIALITY

Please identify any confidential or sensitive information included in your entry. All individuals that can access, view or judge application forms and supporting evidence submitted by competitors will be required to sign nondisclosure agreements. Once entries have been processed they will be kept for twelve months or until there is no reason related to the management of the Longitude Prize for us to keep them.

SUPPORT

Nesta will work with partners to provide support to competing individuals and teams, with the aim of helping competitors gain knowledge and skills in areas where they might lack expertise. This could take the form of workshops on regulatory requirements, business development, intellectual property, and healthcare issues, and mechanisms to help competitors look for collaborators and source necessary external expertise.

LONGITUDE DISCOVERY AWARDS AND LONGITUDE BOOST GRANTS

The original Longitude Prize succeeded in part due to the financial rewards distributed to promising competitors. John Harrison received a large amount of money in 'grants' to help develop his idea. Concurrent with the Longitude Prize we fund early-stage transformative novel approaches with smaller sums of money, meaning that we can create and maintain a broader base of research working towards meeting the aims of the Longitude Prize. We want to encourage as many innovators who are developing novel ideas as possible to enter the Longitude Prize, rather than simply rewarding research which was already in development. These awards are called the Longitude Prize Discovery Awards and the Longitude Boost Grants.

PUBLIC ENGAGEMENT

Antibiotics was voted as the Longitude Prize challenge by the UK public during a phone and online ballot held between 22nd May and the 25th June 2014. We have also heard the opinion of a wide variety of people in focus groups throughout the development of the prize themes. The science and technology that is developed for the Longitude Prize will have a direct impact on the public through health service provision; therefore it is important that a wide variety of people are consulted. The Longitude Prize will continue to facilitate the coming together of the public, scientists and other expert stakeholders to deliberate and reflect on the development of technology that will radically change health care.

PRIZE TERMINATION

We reserve the right to suspend or terminate the Longitude Prize if we determine that the Prize will no longer achieve its aims or is no longer relevant or useful; or if there are changes or developments outside our control that affect the Prize. This includes changes to the applicable law, or in medical, technological or scientific knowledge. Participation in the Longitude Prize is entirely at your own risk.

For further information please see the [Longitude Prize Terms & Conditions](#).

PART 5

OTHER REQUIREMENTS

ETHICS

You must comply with the relevant local laws or regulation governing your research. You are responsible for ensuring that ethical issues relating to your projects are identified and brought to the attention of the relevant approval or regulatory body. Approval to undertake the research must be granted before any work requiring approval begins. Ethical issues should be interpreted broadly and may encompass, among other things, relevant codes of practice, the involvement of human participants, tissue or data in research, the use of animals, research that may result in damage to the environment and the use of sensitive economic, social or personal data. In addition, you must comply with the Helsinki Declaration on Ethical Principles of Medical Research Involving Human Subjects if it provides for a higher standard of protection of humans than the local regulations. If evidence arises that shows that you have acted unethically or illegally, Nesta and the Longitude Committee reserve the right to disqualify you.

ACCESS TO DATA AND INFORMATION

To help ensure that the new knowledge produced as part of the prize has the greatest positive impact, the Longitude Prize strongly encourages the publishing of all non-sensitive research data in order to foster broadest possible access to data in the interest of collaboration, transparency, accountability and enhancing innovation.

We recognise that some data and findings may be commercially sensitive or have implications for individual privacy – in such cases the expectation to make findings publicly available is relaxed. You should provide evidence of your commitment to making data accessible, and provide reasons for why you have not done so in specific cases.

TERMS & CONDITIONS

You must fully comply with our Terms & Conditions.

COMMUNICATION

If you need to communicate with the Longitude Prize please do so using the longitude.prize@nesta.org.uk email address.

You must not attempt to directly contact any external assessors or any of the Prize Advisory Panel or Longitude Committee members on Longitude Prize matters. All communications should be with the Longitude Prize team at Nesta. Any evidence of competitors trying to influence the Panel or Committee members in this way will lead to their disqualification.

KEY TERMS

DESIGN-LOCKED, OPTIMISED

The product's technical and physical design specification is finalised and has been optimised based upon results and feedback from formative evaluations.

GLOBAL

Pertaining to the entire globe rather than a specific region or country.

POINT-OF-CARE

Point-of-care is the specific location at which a patient is presenting with illness – this could be at home, or in a range of primary and secondary healthcare settings. Point-of-care diagnosis therefore takes place close to the patient, rather than at a physically removed central laboratory.

TRANSFORMATIVE

New solutions that will revolutionise the prescribing and use of antibiotics globally rather than incremental changes to existing technologies.



Innovate UK



SCIENCE
MUSEUM

LONGITUDE PRIZE

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