Longitude Prize - Application Form to win

Note: please do not use this PDF to register, it is only provided as a reference. All applications must be submitted using the link sent to you by the Longitude Prize Management team when registering as a Competitor.

Before filling out this application form please refer to Part 3 of the Prize Rules (www.longitudeprize.challenges.org/prize-rules/) The questions in this form have corresponding guidance in the Prize Rules document. Please read this guidance to ensure that your answers are as accurate as possible. This document contains more information on the sections below and should guide your entries.

All entries, including attached material, should be in English. In your entry you should address all of the questions posed. You should be concise and informative.

You may have additional and technically detailed information which supports or is relevant to your answers to the stated questions. Please submit this information with the application form. Clearly name these files including your Team ID, and refer to them and their content in the relevant sections of the application form.

The burden of making a strong case for the suitability of a diagnostic test to win the Longitude Prize is on competitors. This includes supplying relevant information and evidence. Nesta, the Prize Advisory Panel, and the Longitude Committee will make their judgement based upon the information contained in application forms, expert assessment, and further testing. The Prize Advisory Panel may also ask you for further information and/or invite you to interview.

REFERENCING IN YOUR APPLICATION

Please use a consistent referencing style throughout your application.

In your answers please refer to any published material that backs up your claims using the Harvard style referencing system. Include name, page and date of publication in brackets in text e.g. (Brown, p72, 2013) and include a full bibliography of references at the bottom of the application form.

Include any unpublished data or key supporting data as an attachment. In brackets, indicate that the reference material has been uploaded by using the term “ATTACHMENT”. Then include the name, page and date as with Harvard referencing system. E.g. (ATTACHMENT, Brown, p89, 2013) and title the attached material accordingly.

Please provide a full list of all the documents that you have uploaded under the SUPPORTING EVIDENCE section of this application form.

Other creative forms of evidence such as video content are encouraged. This content should be referenced in a similar way to written material.

Before you submit an entry, please ensure that you have carefully read the Longitude Prize Prize Rules, Terms and Conditions, our website Privacy Policy.
CHECKLIST

Do not apply for the Longitude Prize unless your entry meets all of the criteria outlined below:

1. Needed

Focused on a globally–occurring problem. The test must improve the targeted use of antibiotics on common globally–occurring infections (including in the UK) by:

- Ruling out unnecessary antibiotic use, AND/OR
- Providing all of the necessary information to identify an effective antibiotic or combination of antibiotics.
- Able to improve antibiotic treatment decisions. The test must address the described problem appropriately so that it improves antibiotic treatment decisions and public health. The test must improve on currently available existing diagnostic approaches. Your test must not have been commercially available as of 18th November 2014.

2. Accurate

The test must be accurate enough to eliminate harmful treatment decisions, inform more targeted antibiotic use, and give users, e.g. patients, health workers, the confidence to act upon its result.

3. Affordable

At forecasted full scale manufacture the test, including any instrumentation, must be affordable for purchase and use in its intended global market(s). Less expensive tests will be favoured. Please provide evidence of affordability in each multiple applicable markets.

4. Rapid

The time from sample collection to reporting of the result to the treatment decision–maker must be less than thirty minutes. More rapid tests will be favoured.

5. Easy-to-use

Globally applicable - the test must be suitable for point–of–care use in as many global healthcare settings where the test could be used to inform treatment decisions as possible.

Minimally reliant on healthcare resources - the test must require minimal healthcare resources and training to be used effectively and safely.

Easy-to-use and interpret - the test must be easy to use and interpret safely and effectively, in the global settings and locations where it will be used. Please provide evidence to support your claim that the relevant user of the test would be able to use it effectively. Please consider issues of language and literacy.

6. Scalable

Ready for manufacture and distribution - there must be a feasible product commercialisation plan for full–scale manufacture and global distribution.

Original - you must take reasonable steps to find out whether your technology infringes on the intellectual property rights of others.

7. Safe

The risks associated with a test will be judged against the benefit it can provide. Please tell us the main risks associated with your test and how you would address each of these.

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). Please submit a video or photographs or other image of your prototype with your application showing dimensions, with scale, and also tell us its weight.
PART 1: TEAM DETAILS

Name of the team leader *

Country where your team is based *

Please name the organisation(s) that are represented in your team

Where applicable please provide the registration number

Please list the name, organisation and profession of team members

Please list team members one per line, for example:
A White, Nesta, Microbiologist

How long has your team been developing your idea?

☐ 0-1 years
☐ 2-3 years
☐ 4-5 years
☐ 6-7 years
☐ 8+ years

Eligibility criteria

To compete in the Longitude Prize you must be able to demonstrate that in winning the 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 which 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:

- carry out manufacturing and/or design of the winning solution in the UK, or
- lab test or showcase the winning solutions in the UK, or
- use some other means agreed in writing with Nesta and Innovate UK before participating in the Longitude Prize.
Please outline how you meet the eligibility criteria *

Limit: 200 words

Non-technical summary of proposed project *

Limit: 400 words

PART 2: TECHNOLOGY / PRODUCT DESCRIPTION

Please describe how your diagnostic test works, including an overview of its operational processes and the science and technology upon which it is based.

Also provide a brief intended use statement describing how it will be used, for what condition or conditions, and where.

Please submit a product specification profile which gives a summary of the key performance and operation characteristics. These profiles are flexible, but typically include brief requirements for specificity, sensitivity, time to result, throughput, specimen type, sample preparation, number of samples, readout, waste disposal, controls, reagents, storage/stability, instrumentation, power requirement, training, and cost.

Your application in Part 2 must be a maximum of 40 A4 pages, must stick to the word limits stated, size 11 point font. This does not include Supporting Evidence.

Product description *

Limit: 700 words

The technology/product description section is to allow a quick overview – please do not go into the detail behind your values. You will be asked for supporting evidence later in the application form.

A: NEEDED

Please refer to sections A, A1 and A2 in the prize rules

A1: FOCUSED ON A GLOBALLY–OCCURRING PROBLEM

In the corresponding boxes below please answer the following questions with reference to your diagnostic test:

Question 1
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

Question 2
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 evidence, data or studies that demonstrate disease burden or any other relevant information that demonstrates a pressing need in relation to antibiotic resistance.
Question 3
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.

Question 4
Describe any relevant, existing, comparative 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.

Question 5
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, e.g. 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.

Please attach and clearly name any detailed material that supports your answers. Supporting evidence can be uploaded at the end of the online submission form.
A2: ABLE TO IMPROVE ANTIBIOTIC TREATMENT DECISIONS

In the space provided below, explain how the test will specifically address the above-outlined problem(s). This must include details of:

Question 1
How will the submitted diagnostic test improve the targeted use of antibiotics?

Question 2
How will the submitted test improve upon existing diagnostics in this field? Please outline the best alternative and most commonly used alternatives (either point-of-care or lab-based testing).

Question 3
How will the test fit into or change the treatment decision process. If the process varies across different settings, please describe the most widespread processes. Please attach and clearly label an outline patient pathway for the diagnostic test as part of your supporting evidence. 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.

Question 4
How will the test address the behavioural drivers of the problem across the different locations at which the infection has significant incidence, e.g. 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?

Question 5
Please provide details of 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.

Question 1 *

Limit: 300 words

Please attach and clearly name any detailed material that supports your answers. Supporting evidence can be uploaded at the end of the online submission form.

Question 2 *

Limit: 300 words

Question 3 *

Limit: 300 words

Question 4 *

Limit: 300 words
Question 5 *

Flowchart to describe test use *

Acceptable file types: pdf, doc, docx, jpg, jpeg, gif, png.

Choose Files

Please upload a flowchart or video outlining the process for how your test is to be used. Your answer should demonstrate how the test will influence the treatment pathway for antibiotic prescribing.

No files have been attached yet.

B: ACCURATE

Please refer to Section B in the Prize Rules for guidance.

In the space provided below, you must provide:

Part A
Sensitivity and specificity values for your diagnostic test and the positive and negative predictive values, where available. Please include a brief 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.

Part B
A description of the range of analytes over which there is an accurate result and which standard your diagnostic accuracy is measured against.

Part C
A summary of any local conditions, such as diet, comorbidities, or anything else, which affects the accuracy of your test.

Part D
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.

Part A *

Please attach and clearly name any detailed material that supports your answers. Supporting evidence can be uploaded at the end of the online submission form.

Part B *
C: AFFORDABLE

Please refer to Section C in the Prize Rules for guidance.

In the space below you must explain how your diagnostic test will be affordable in its intended global markets by showing how it:

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

To support these claims you must provide the following information with reference to your diagnostic test:

Part A
Give the projected unit cost at production scale of 10,000 units – this must take account of the estimated direct and indirect costs including 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.

Part B
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.

Part C
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, such as the cost of the antibiotic or treatments that that test might save, and stipulate the cost of the existing diagnostic methods for the infection(s).

Part A *

Part B *
Part C *

D: RAPID

Please refer to Section D in the Prize Rules for guidance.

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

Part B
In many instances, depending on the context, a test may need to be significantly quicker than 30 minutes to be clinically useful. Explain how the time to result of your test will be appropriate for its intended use.

Part A *

Please attach and clearly name any detailed material that supports your answers. Supporting evidence can be uploaded at the end of the online submission form.

Part B *

E: EASY TO USE

Please refer to Section E, E1 and E2 in the Prize Rules for guidance.

E1: 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).
E2: MINIMALLY RELIANT ON HEALTHCARE RESOURCES

In the space provided below, you must provide relevant information under each of the categories. 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.

1. Calibration requirements and controls.

2. Specimen type, volume, and collection method.

3. Sample preparation (steps, biosafety, precision required, time sensitivity).

4. Waste disposal (safety, ease, environmental acceptability).

5. Reagents required (availability, inclusion).


7. Instrumentation (maintenance requirements, replacement cost, size, shock resistance).

8. Power requirement.

9. Training required (mode, level, and length).

10. Intended user (trained laboratory worker, primary care doctor, untrained patient, etc.).

11. Portability and size (weight).

Please clearly label your responses 1 through 11 to match the sections in E2 above.

E3: EASY–TO–USE AND INTERPRET

In the space provided below, you must submit:

Part A
A description of conditions of use that might affect test use safety or effectiveness, including behavioural and cultural practices;

Part B
A summary of the characteristics of intended use environments that could impact use (e.g., glare, vibration, ambient noise, etc.); any environments for which the test is unsuited should be stated;

Part C
The known use problems with previous models of the same test (as applicable) or problems with similar types of medical devices;

Part D
Any design modifications of the current device that were specifically developed in response to use problems in the field;

Part E
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

Part F
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

Please refer to Section F in the Prize Rules for guidance.

You must attach a product commercialisation plan as supporting evidence to validate your claims. You do not have to follow a specific template. However, you must include convincing and detailed answer to all of the questions below:

**Operations, financial and marketing plan**

You must outline the operational (purchasing, distribution, manufacturing etc.), financial (statements, forecasts, assumptions, funding etc.) and marketing (tactics, sales etc.) plans to get your diagnostic to market. Forward projections should cover at least a five–year period.
• What is your business model (i.e. strategy)?

• How will you move to quality assured full-scale manufacture?

• How will you distribute the diagnostic test to the settings in which it is needed, including low-income countries?

• How will you ensure the long-term sustainability of the solution in different marketplaces?

• How will you meet regulatory approval so that you can sell your test in the nations where it is needed?

• How will you ensure that at point of purchase the diagnostic test is below the price point, including in low-income countries?

• What are the risks involved in the business plan and how will they be mitigated?

Market analysis

• What is your competitive landscape?

• For target market size, demographics, trends and growth refer to your answers in Section A: Needed and Section C: Affordable

Intellectual Property

• Have you taken steps to ensure you’re not infringing anyone else’s intellectual property?

• Have you taken any steps towards protecting your intellectual property?

• Have you structured your intellectual property schemes such that end-users will be able to affordably and easily access your test?

Product Commercialisation Plan *

Please upload your product commercialisation plan.

Acceptable file types: pdf, doc, docx.

Choose Files

G: SAFE

Please refer to Section G in the Prize Rules for guidance.

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

• 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.

• Public health impact of incorrect result (false negative and false positive).

• Individual health impact of incorrect result (false negative and false positive).

• Safety concerns (those not associated with incorrect results i.e. risk of contamination from sample).

Risk Framework *

Please upload your risk framework.

Acceptable file types: pdf, doc, docs, txt, rtf, wpf, odt, wpd.
H: CONNECTED

Please refer to Section H in the Prize Rules for guidance.

In the space below, please describe 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.

Answer *

Please attach and clearly name any detailed material that supports your answers. Supporting evidence can be uploaded at the end of the online submission form.

OPEN ACCESS

In Part 5 of the Prize Rules 'ACCESS TO DATA AND INFORMATION' we outline our commitment to encouraging open access to scientific data.

Answer *

In the space provided, please describe any commitment to open access, including previous instances in which you have made your work openly available and plans for doing so in the future. If there are notable pieces of work which you do not plan to make openly available, please explain why.

BIBLIOGRAPHY

Please list your full bibliography here

Limit: 500 words

SUPPORTING EVIDENCE *

Please make a full list of all the documents you have uploaded as supporting evidence here.

Limit: 400 words

Prototype size / dimensions and weight *

Please provide details of the dimensions (in millimetres) and weight (in grams) of your prototype, to include any additional attachments or plug-ins required for the test to be fully used.

Please note that if your application is forwarded to our judging panel, we may ask you to send one copy of your prototype to us. We will only ask you to do this if your prototype is small enough to fit within a standard UK C5 sized envelope (dimensions: 162 x 229mm).
Please upload up to three images of your prototype. Select up to 3 files to attach. No files have been attached yet.

Please upload any supporting evidence for your entry. Ensure that all file names match those referenced in the body of your application and those listed in the supporting evidence section. Select up to 10 files to attach. No files have been attached yet.